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SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1985

KATHLEEN N. MILLS

AND

MICHAEL WAYNE MILLS

VERSUS

UNITED STATES OF AMERICA

ON WRIT OF CERTIORARI TO THE

UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

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QUESTIONS PRESENTED

1. Whether there is a conflict between the decisions of the United States Court of Appeals for the Fifth Circuit which denied recovery under the Swine Flu Act (42 U.S.C. 247(b), et seq) even though the proven cause of death of petitioners' decedent was the swine flu inoculation, and the decisions of the Courts of Appeal for the Eighth and Tenth Circuits, which permitted recovery under similar circumstances.

2. Whether the action of the United States under the Swine Flu Act, 42 U.S.C. 247(b) et seq, through the Department of Health, Education and Welfare, voluntarily compensating victims of Guillain-Barre Syndrome (GBS) caused by the swine flu inoculation but refusing to pay victims of other diseases and reactions caused by such inoculation constitutes discrimination prohibited by the Fifth Amendment of the United States Constitution.

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1985

NUMBER _____

KATHLEEN N. MILLS AND

MICHAEL WAYNE MILLS,

Petitioners

VS.

UNITED STATES OF AMERICA,

Respondent

PETITION FOR A WRIT OF CERTIORARI
To the United States Court of Appeals
for the Fifth Circuit.

Petitioners, Kathleen N. Mills and Michael Wayne Mills, pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Fifth Circuit entered August 13, 1985, which reversed the judgment in

favor of petitioners rendered by the United States District Court for the Western District of Louisiana, Monroe Division, and that on hearing, the judgment of said Court of Appeals be reversed and the judgment of the United States District Court for the Western District of Louisiana be reinstated and affirmed.

QUESTIONS PRESENTED

1. Whether there is a conflict between the decision of the United States Court of Appeals for the Fifth Circuit which denied recovery under the Swine Flu Act (42 U.S.C. 247(b), et seq) even though the proven cause of death of petitioners' decedent was the swine flu inoculation, and the decisions of the Courts of Appeal for the Eighth and Tenth Circuits, which permitted recovery under similar circumstances.

2. Whether the action of the United

States under the Swine Flu Act, 42 U.S.C. 247(b) et seq, through the Department of Health, Education and Welfare, voluntarily compensating victims of Guillain-Barre Syndrome (GBS) caused by the swine flu inoculation but refusing to pay victims of other diseases and reactions caused by such inoculation constitutes discrimination prohibited by the Fifth Amendment of the United States Constitution.

PARTIES TO THIS PROCEEDING

The only parties to this proceeding are set forth in the caption of the case in this Court.

OPINIONS BELOW

The opinions of the United States District Court for the Western District of Louisiana are unreported and copies are attached in the Appendix (App. p.) as is a copy of the denial of rehearing (App. p.). The opinion of the Court of

Appeals for the Fifth Circuit is reported at 764 F.2d 373, and a copy is in the Appendix (App. p. __). A copy of the administrative ruling of the Department of Health, Education and Welfare is set forth in the Appendix (App. p.).

GROUNDS ON WHICH THE JURISDICTION OF THIS COURT IS INVOKED

Applicants seek the review of the decision of the Court of Appeals for the Fifth Circuit in the case entitled "Mrs. Kathleen N. Mills and Michael Wayne Mills v. United States of America" decided on July 1, 1985, which case is reported in 764 F2d 373. Timely application for rehearing en banc was filed and was denied August 13, 1985. This court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL, STATUTORY AND ADMINISTRATIVE PROVISIONS INVOLVED

This case involves the Swine Flu Act of 1976, 42 U.S.C. 247(b) et seq, the Administrative Ruling of the Department

of Health, Education and Welfare, and the Fifth Amendment to the United States Constitution (App. pp.).

STATEMENT OF THE CASE

Pursuant to the Swine Flu Act of 1976, The United States, through the Department of Health, Education and Welfare, instituted a program of mass immunization against swine flu. A massive propaganda campaign was mounted in an attempt to inoculate the entire population of the nation. Immediately after the implementation of the program, illnesses and deaths occurred which were cuased by the vaccination. The propaganda persuaded Warren W. Mills, the husband and father, respectively, of petitioners, to obtain the inoculation at the Madison Parish, Louisiana Public Health Clinic. He became a victim of the vaccine, suffering an anaphylactic reaction which precipitated an

anaphylactic shock and myocardial infarction from which he died within minutes of receiving the inoculation. It is the law of the case, not contested by the government on appeal, that the swine flu inoculation was the cause of Mills' death.

The United States voluntarily admitted liability to all vaccinees sustaining injury or death from Guillain-Barre Syndrome caused by the vaccination but denied liability to all other victims even though the injury or death was also caused by the inoculation.

Pursuant to the directive of the Swine Flu Act, the government attempted to formulate a "consent form" labeled "Registration Form", which all vaccinees were required to sign as they proceeded through the line to receive the inoculation.

In a bifurcated trial the United

States District Court for the Western District of Louisiana held that the swine flu vaccine was the cause in fact of Mills' death, that the United States was liable, and awarded damages to Mills' widow and son. The Fifth Circuit reversed on the theory that under the Louisiana Uniform Consent Law (LSA R.S. 40:1299.40), the general language in the registration form advising of possible allergic or severe reactions was sufficient to warn Mills of the danger of anaphylaxis, anaphylactic shock and myocardial infarction.

The Eighth Circuit Court of Appeals, interpreting an Iowa statute identical in pertinent part to the Louisiana statute, had previously reached the opposite conclusion in upholding an award in a case involving a heart attack resulting from serum sickness caused by the swine flu inoculation. Petty v. United States,

536 F.S. 860 (ND Iowa, 1980); remanded for further consideration 679 F2d 719 (CA 8, 1982); reinstated after remand 592 F.S. 687 (ND Iowa, 1983); affirmed 740 F.2d 1428 (CA 8, 1984). The state consent statute in both Louisiana and Iowa followed the "Uniform Act".

The Tenth Circuit Court of Appeals also previously had reached a conclusion opposite to that reached by the Fifth Circuit, in a case involving transverse myelitis. Unthank v. United States, 533 F.S. 703 (D, Utah, 1982); affirmed 732 F.2d 1517 (CA 10, 1984).

The Eighth and Tenth Circuits held that the government's misguided propaganda campaign misinformed the victims of the vaccine of the dangers of not taking the shot rather than the dangers of receiving the inoculation, and misstated the necessity for the vaccination, and held that the

Congressional intent was to compensate and treat equally all persons who proved death or injury caused by the swine flu inoculation, irrespective of the particular reaction.

The decision of the government voluntarily to pay victims of Guillain-Barre Syndrome caused by the swine flu inoculation was based on the fact that Guillain-Barre Syndrome was not specifically mentioned in the Registration form although the form provided that "the possibility of severe or potentially fatal reactions exist". Voluntary payment was made to all victims of Guillain-Barre Syndrome <u>regardless of the consent laws of the individual states in which the cases arose</u>.

Guillain-Barre Syndrome is an antigen-antibody reaction in which the body's defense mechanism goes amuck and attacks the insulation on the peripheral

nerves. It is caused by sensitivity to the vaccine or other protein. Anaphylaxis, which Mills sustained, is also caused by hypersensitivity to vaccine or other protein with resulting antigen-antibody reaction, the release of histamine and a resulting breakdown of the body's circulatory system. In the Petty case the hypersensitivity to the vaccine induced an antigen-antibody reaction resulting in serum sickness and a heart attack. In Unthank the same type of reaction resulted in transverse myelitis, involving the central nervous system. In those cases the Eighth and Tenth Circuits ordered the Government to compensate the victims.

All such conditions - Guillain-Barre Syndrome, transverse myelitis, serum sickness and anaphylaxis are severe and potentially fatal and all are extreme allergic reactions. As the record shows,

all were known and expected reactions to the swine flu vaccine.

The jurisdiction of the court of first instance was based on the Swine Flu Act of 1976, 42 U.S.C. 247(b), et seq, and the Federal Tort Claims Act, 28 U.S.C. 2671-2680 and 28 U.S.C. 1346b.

REASONS FOR GRANTING THE WRIT

A. THE CONFLICT BETWEEN CIRCUITS

This court should resolve the conflict between the Fifth Circuit on the one hand and the Eighth and Tenth Circuits on the other. A mass immunization program is not local in nature, and it is important that it be administered uniformly and fairly throughout the United States. Undoubtedly similar programs will be initiated in the future in connection with other diseases - AIDS, for example. It will be much easier in the future to secure the cooperation of the populace if they know in advance

what to expect from their government should their participation in a program result in injury or death.

The conflict between the Circuits is real. In the instant case the Fifth Circuit construed the language in the Government's Registration Form, advising of the possibility of allergic or potentially severe or fatal reactions, as adequate under the Louisiana Consent Law (LSA R.S. 40:1299.40) to warn Mills of the dangers of anaphylactic reaction and myocardial infarction The Iowa consent statute (involved in the Petty case) is identical in pertinent part to the Louisiana statute as indicated:

LOUISIANA	IOWA
"Notwithstanding any other law to the contrary, written consent to medical	"A consent in writing to any medical or surgical procedure or course

treatment means a consent in writing to any medical or surgical procedure or course of procedures which (a) sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, of disfiguring scars associated

of procedures in patient care which meets the requirements of this section shall create a presumption that informed consent was given. A consent in writing meets the requirements of this section if it:

1. Sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia,

with such procedure or procedures . . . ."	paraplegia, the loss or loss of function of any organ or limb, or disfiguring scars associated with such procedure or procedures. . ."

A severe allergic reaction was sustained by both Mills and Petty, both resulting in heart attacks. If the warning was inadequate for Petty it was equally inadequate for Mills. No logical medical or practical distinction can be made between the reactions sustained by the victims in the two cases - both were antigen-antibody induced (allergies) and both were severe and potentially fatal. The rationale of the Fifth Circuit decision would have denied recovery to GBS victims in Louisiana absent the admission of liability of the Government

in such cases.

Although no uniform consent statute was involved in the decision of the Tenth Circuit in the Unthank case, such case also is in conflict with the decision in this Mills case. As in this Mills case, there was no specific warning of the danger of transverse myelitis sustained by Unthank and the court held that the general warning of "allergic or potentially fatal reaction" did not adequately warn of the danger of transverse myelitis. Transverse myelitis is also an antigen-antibody (allergic) reaction.

The so-called "consent form" put out by the Government, but which actually is nothing more than a "registration form" has been held by the Tenth Circuit, in the Unthank case, to be inadequate for all purposes. The Unthank opinion, 732 F. 2d at 1521 and 1522 said this:

"While the Swine Flu Act adopts by reference the laws of the jurisdictions in which the cause of action arises it is nonetheless the act itself which determines the basis for that adoption and the question of whether those state laws should be construed narrowly or liberally. We believe that in cases arising out of the Swine Flu Act, underlying state laws must be liberally construed in favor of claimants....."

That Court also adopted the theory that the massive propaganda campaign carried on by the Government vitiated any warning or implied consent given in the registration form, saying, page 1521:

".....the setting for the Swine Flu program was so extraordinary that other cases can provide no real precedence. However, the setting cannot be ignored in interpreting the reasonableness of the consent obtained from those who contracted anticipatable and clearly provable maladies as a direct consequence of responding to the urgings of the federal government for the people to participate.....

"So monumental and effective were the urgings of the Government that it resulted in an unprecedented nearly 40 million citizens responding to the call. Both this plaintiff and untold others relied

on the Government's assurances that the vaccine was both safe and necessary.

"A barrage of publicity aimed at overcoming the reluctance of citizens to participate included the unprecedented appearance of the President of the United States on national television to plead for a positive response. Against that background, it would be a travesty to suggest that people who hurriedly signed the standardized form presented to them were adequately informed of the risks.

"Even the Secretary (of Health, Education and Welfare) conceded that the general language of the consent form was inadequate, at least as to GBS. In the face of the barrage of urgings from the authorities of the United States Government, it would defy logic and reason to suggest that an adequate warning was provided by the mere mention in the consent form's text that there was a "possibility of severe or potentially fatal reaction." Perhaps in another context such a generalized, uninformative statement might satisfy Utah and federal law, but we cannot conclude that in the factual setting in which this program and in which this plaintiff specifically participated, that warning was "informed" for purposes of the Act."

B. FIFTH AMENDMENT VIOLATION

As to the question of discrimination

prohibited by the Fifth Amendment of the United States Constitution, the intent of Congress in enacting the Swine Flu Act should be considered. Section k(1)(A)(ii) provides:

> "The Congress finds that ..... in order ..... (k)(1)(A)(ii) to provide such protection and to establish an orderly procedure for the prompt and equitable handling of claims by persons alleging such injury or death, it is necessary that an exclusive remedy for such claimants be proved against the United States because of its unique role in the initiation, planning, and administration of the swine flu program;"

The intent of Congress was to compensate all victims of injury or death who could prove such injury or death was caused by the swine flu inoculation. This was so held by the Tenth Circuit in Unthank, which court quoted from remarks made before the Congressinal Committee in debating the Act (732 F 2d 1517 at pp. 1519 and 1520):

"This is pioneering in the sense, it

has never been done before, but it is in response to an emergency. That is the way the liability fixes upon the government, through the total class act, for any misforture which would follow, as defined, the administration of the inoculation and vaccine....."

"[W]e have asked the drug companies to produce this vaccine. We have told them how to do it. We have told them the dosage we want, what strength. We gave them the specifications because we are the only buyers, the Government of the United States. This is not the usual process of going out and selling. But if someone is hurt, we think people ought to have a remedy."

The Unthank opinion, 732 F 2d 1522, also stated:

"The trial court's further recitation of the congressional record and the milieu in which all of this took place supports the conclusion that the trial court's only real concern was about causation. The trial court correctly concluded that there was sufficient information prior to 1976 that a neurological disorder such as transverse myelitis was a recognized risk of influenza vaccination. 533 F.Supp. at 720. Tying that recognized fact to the statements in the congressional record, it is overwhelmingly clear that Congress intended people who suffered from

> these consequences to be compensated. It must be remembered that Congress acted in the face of the fact that the manufacturers and the insurance carriers of all kinds so clearly recognized the risks that they were unwilling to proceed."

There is no logical basis for the government to have restricted voluntary compensation to victims of GBS. GBS is an allergic reaction as is anaphylaxis; both are severe and potentially fatal; neither was specifically designated as a possible side effect or hazard on the government form; and both were well known to the medical community as foreseeable reactions to the swine flu inoculation. To voluntarily pay victims of GBS while denying compensation to victims of other reactions to the swine flu inoculation is

gross discrimination, prohibited by the Fifth Amendment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

We certify that a copy of the above and foregoing has been served this day, by prepaid parcel post, to the Solicitor General, Department of Justice, Washington, D.C. 20530, to Laura D. Millman, Trial Attorney, Torts Branch, Civil Division, U. S. Department of

Justice, Washington, D.C. 20530, and D. H. Perkins, Assistant United States Attorney, Room 3B12, Federal Building, 500 Fannin Street, Shreveport, Louisiana 71101.

November 8, 1985.

Thomas M. Hayes, Jr.

Edgar H. Lancaster, Jr.

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Public Law 94-380

94th Congress, S. 3735

August 12, 1976

An Act

To amend the Public Health Service Act to authorize the establishment and implementation of an emergency national swine flu immunization Program and to provide an exclusive remedy for Personal injury or death arising out of the manufacture, distribution, or administration of the swine in vaccine under such program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be

Immunization Program of 1976. Sec.2 Section 317 of the Public Health Service Act (42 U.S.C. 247b) is amended by inserting after subsection (i) the following new subsections:

(j)(1) The Secretary is authorized to establish, conduct, and support (by grant or contract)needed activities to carry out a national swine flu immunization program until August 1, 1977 (hereinafter in this section referred to as the "swine flu program"). The swine flu program shall be limited to the following:

(A) The development of a safe and effective swine flu vaccine.

(B) The prepration and procurement of such vaccine in sufficient quantities

the States.

(C) The making of grants to State health authorities to assist in meeting their costs in conducting or supporting, or both, programs to administer such vaccine to their populations, and the furnishing to State health authorities of sufficient quantities of such swine flu vaccine for such programs.

(D) The furnishing to Federal health authorities of appropriate quantities of such vaccine.

(E) The conduct and support of training of personnel for immunization activities described in subparagraphs (C) and (D) of this paragraph and the conduct and support of researce on the nature, cause, effect of the influenza against

immunize, the nature and effect of such vaccine, immunization against and treatment of such influenza, and the cost and effectiveness of immunization programs against such influenza.

(F) The development, in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Researce, and implementation of a written informed consent form and Procedure for assuring that the risks and benefits from the swine flu vaccine are fully explained to each individual to whom such vaccine is to be administered. Such consultation shall be completed within two weeks after enactment of this Act or by September 1, 1976, whichever is sooner. Such procedures shall include

viduals with respect to their rights and remedies arising out of the administration of such vaccine.

(G) Such other activities as are necessary to implement the swine flu Program.

"(2) The Secretary shall submit quarterly reports to the Congress on the administration of the swine flu program. Each such report shall provide information on--

"(A) the current supply of the swine flu vaccine to be used in the program;

"(B) the number of persons inoculated with such vaccine since the last report was made under this paragraph and the immune status of the population;

"(C) the amount of funds expended for the swine flu program by the United

for the swine flu program by the United States, each State, and any other entity Participating in the program and the costs of each such participant which are associated with the program, during the period with respect to which the report is made; and

(D) The epidemiology of influenza in the United States during such period.

"(3) Any contract for procurement by the United States of swine flu vaccine from a manufacturer of such vaccine shall (notwithstanding any other provision of law) be subject to renegotiation to eliminate any profit realized from such procurement (except that with respect to vaccine against the strain of influenza virus known as influenza A/Victoria/73

profit shall be allowed but limited to an amount not exceeding a reasonable profit), as determined pursuant to criteria prescribed by the Secretary, and the contract shall expressly so provide. Such criteria shall specify that any insurance premium amount which is included in the price of such procurement contract and which is refunded to the manufacturer under any retrospective, experience rating plan or similar rating plan shall in turn be refunded to the United States.

"(4) No funds are authorized to be appropriated to carry out the activities of the swine flu program authorized in subparagraphs (A),(B),(D),(E), and (F) of paragraph (1) of this subsection in addition to funds appropriated by Public Law 94-266.

"(k)(1)(A) The Congress finds that-"(i) in order to achieve the participation in the program of the agencies, organizations, and individuals who will manufacture, distribute, and administer the swine flu vaccine purchased and used in the swine flu program and to assure the availabity of such vaccine in interstate commerce, it is necessary to protect such agencies, organizations, and individuals against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of such vaccine.

"(ii) in order to provide such protection and to establish an orderly procedure for the prompt and equitable handling of claims by persons alleging such injury or death, it is necessary that an exclu-

sive remedy for such claimants be provided against the United States because of its unique role in the initatation, planning, and administration of the swine flu program; and

"(iii) in order to be prepared to meet the potential emergency of a swine flu epidemic, it is necessary that a procedure be instituted for the handling of claims by persons alleging such injury or death until Congress develops a permanent approach for handling claims arising under the programs of the Public Health Service Act.

"(B) To--

"(i) assure an orderly procedure for the prompt and equitable handling of any claim for personal injury of death arising out of the administration of such vaccine; and

"(ii) achieve the participation in the swine flu program of

(I) the manufacturers and distributors of the swine flue vaccine,

(II) public and private agencies or organizations that provide inoculations without charge for such vaccine or its administration and in compliance with the informed consent form and procedures requirements prescribed pursuant to subparagraph (F) of paragraph (1) of this subsection, and (III) medical and other health personnel who provide or assist in providing inoculations without charge for such vaccine or its administration and in compliance with such informed consent form and procedures requirements, it is the purpose of this subsection to establish a procedure under which all such claims will

be asserted directly against the United States under section 1346(b) of title 28. United States Code, and chapter 171 of such title (relating to tort claims procedure) except as otherwise specifically provided in this subsection.

"(2)(A) The United States shall be liable with respect to claims submitted after September 30, 1976 for personal injury or death arising out of the administration of swine flu vaccine under t@e swine flu program and based upon the act or omission of a Program participant in the same manner and to the same extent as the United States would be liable in any other action brought against it under such section 1346(b) an chapter 171, except that --

"(i) the liability of the United States arising out of the act or omission of a program participant may be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty;

"(ii) the exceptions specified in section 2680(a) of title 26, United States Code, shall not apply in an action based upon the act or omission of a program participant; and

"(iii) notwithstanding section 2401(b) of title 26, United States Code, if a civil action or pro-

ceeding for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program is brought within two years of the date of the administration of such vaccine and is dismissed because the plaintiff in such action or proceeding did not file an administrative claim with respect to such injury or death as required by such chapter 171, the plaintiff in such action or proceeding shall have 30 days from the date of such dismissal or two years from the date the claim arose, whichever is later, in which to file such administrative claim.

"(B) For purposes of this subsection, the term program participant as to

any particular claim means the manufacturer or distributor of the swine flu vaccine used in an inoculation under the swine flu program, the Public or private agency or organization that provided an inoculation under th swine flu program without charge for such vaccine or its administration and in compliance with the informed consent form and procedure requirements prescribed pursuant to subparagraph (F) of paragraph (1) of this subsection, and the medical and other health Personnel who provided or assisted in Providing an inoculation under the swine flu Program without charge for such vaccine or its administration and in compliance with such informed consent form and procedure requirements.

"(3) The remedy against the United States prescribed by paragraph (2) of this

subsection for personal injury or death arising out of the administration of the swine flu vaccine under the swine flu program shall be exclusive of any other civil action or proceeding for such personal injury or Government (as defined in section 2671 of title 28, United States Code) or program Participant whose act or omission gave raise to the claim.

"(4) The Attorney General shall defend any civil action or proceeding brought in any court aggianst any employee of the Government (as defined in such section 2671) or program participant (or any liability insurer thereof) based upon a claim alleging personal) injury or death arising out of the administration of vaccine under the swine flu program. Any such person against whom such civil action

or proceeding is brought shall deliver all process served upon him (or an attested true copy thereof) to whoever is designated by the Secretary to receive such Papers, and such person shall promptly furnish copies of the pleadings and process therein to the United States attorney for the district embracing the place wherein the civil action or proceeding is brought, to the Attorney General and to the Secretary.

"(5)(A) Upon certification by the Attorney General that a civil action or action or proceeding brought in any court against any employee of the Government (as defined in section 2671) or program Participant is based upon a claim alleging personal injury or death arising out of the administration of vaccine under the

swine flu program, such action or proceeding shall be deemed an action against the United States under the provisions of title 28, United States Code, and all references thereto. If such action or proceeding is brought in a district court of the United States, then upon such certification the United State shall be substituted as the party defendant,

"(B) Upon a certification by the Attorney General under subparagraph (A) of this paragraph with respect to a civil action or proceeding commenced in a State court, such action or proceeding shall be removed, without bond at any time before trial, by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and be deemed an

action brought against the United States under the provisions of title 28, United States Code, and all references thereto; and the United States shall be substituted as the party defendant. The certification of the Attorney General with respect to program participant status shall conclusively establish such status for purposes of such initial removal. Should a district court of the United States determine on a hearing on a motion to remand held before a trial on the merits that an action or proceeding is not one to which this subsection applies, the case shall be remanded to the State court.

"(C) Where an action or proceeding under this subsection is precluded because of the availability of a remedy through proceedings for compensation or other

beneifts from the United States as provided by any other law, the action or proceeding shall be dismissed, but in that event the running of any limiation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this subsection.

"(6) A program participant shall cooperate with the United States in the processing or defense of a claim or suit under such action 1346 (b) and chapter 171 based upon alleged acts or omissions of the program participant. Upon the motion of the United States or any other party, the status as a program participant shall be revoked by the district court of the

United States upon finding that the program participant has failed to so cooperate, and the court shall substitute such former participant as the party defendant in place of the United States and, upon motion, remand any such suit to the court in which it was instituted.

"(7) Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative settlement or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as any costs of litigation resulting from the failure of any program participant to carry out any obligation or responsibility in connection with the swine flu program.

The United States may maintain such action against such program participant in the district court of the United States in which such program participant resides or has its principal place of business.

"(8) Within one year of the date of the enactment of the National Swine Flu Immunization program of 1976, and semiannually thereafter, the Secretary shall submit to the Congress a report on the conduct of settlement and litigation activities under this subsection, specifying the number, value, nature, and status of all claims made thereunder, including the status of claims for recovery made under paragraph (7) of this subsection and a detailed statement of the reasons for not seeking such recovery.

"(9) For the purposes of subsections (j) and (k) of this section--

"(1) the phrase arising out of the admnistration with reference to a claim for Personal injury or death under the swine flu program include a claim with respect to the manufacture or distribution of such vaccine in connection with the provision of an inoculation using such vaccine under the swine flu program;

"(2) the term 'State' includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands; and

"(3) the term 'swine flu vaccine' means the vaccine against the strain of influenza virus known as influenza A/New Jersey/70 (Hsw 1N1), or a combination of such vaccine and the vaccine against the strain of influenza virus known as influenza A/Victoria/75".

Sec.3. The Secretary of Health, Education and Welfare shall conduct, or provide for the conduct of a study of the scope and extent of liability for personal injuries or death arising out of immunization programs and of alternative approaches to providing Protection against such liability (including a compensation system) for such injuries. Within one year of the date of the enactment of this Act, the Secretary shall report to the Congress the findings of such study and such recommendations) as the Secretary deems appropriate.

Approved August 12, 1976.

Administrative order of Department
of Health, Education & Walfare

STATEMENT OF SECRETARY OF DEPARTMENT OF HEALTH, EDUCATION AND WELFARE RE LIABILITY TO VICTIMS OF GUILLAIN-BARRE SYNDROME

"Secretary Califano stated thst with respect to those alleging GBS, the government was adopting a new policy. Persons who contracted GBS from the swine flu vaccine, in order to receive federal compensation:

> [W]ill not need to prove negligence by Federal workers or others in the Swine Flu Program as required by Federal law and the law in many states. Instead claimants in most cases need to show only that they in fact developed Guillain-Barre as a result of a Swine Flu vaccination and suffered the alleged damage as a result of that condition.

"Secretary Califano set out two reasons for adoption of this policy:

"First, the informed consent form... did not warn individuals that there was a one in one hundred thousand risk that a person receiving a flu shot would contract Guillain-Barre and that one in every two million would die from the condition...Second, in the Swine Flu program, the Federal Government, in an unprecedented effort, actively urged millions of Americans to get flu vaccination shots and funded the nationwide campaign.

"Thus we have decided to provide just compensation for those who contracted Guillain-Barre as a result of the Swine Flu program rather than force many individuals to prove government negligence in protracted proceedings."

(Statement of Secretary Califano, June 20, 1978).

Fifth Amendment, United States Constitution

AMENDMENT [V.]

CAPITAL CASES; DOUBLE JEOPARDY; SELF-INCRIMINATION; DUE PROCESS; JUST COMPENSATION FOR PROPERTY

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

Administrative Ruling

DEPARTMENT OF HEALTH, EDUCATION

AND WELFARE

OFFICE OF THE SECRETARY

WASHINGTON, D. C. 20201

Office of the

General Counsel

MAY 10 1978

CERTIFIED MAIL --

RETURN RECEIPT REQUESTED

E. H. Lancaster, Jr., Esquire

Lancaster, Baxter & Seale

Tallulah, LA 71282

Dear Mr. Lancaster:

We regret to inform you that we cannot allow your client's claim for wrongful death allegedly resulting from the administration of the swine flu vaccine under the National Swine Flu Immunization Program of 1976 (Public Law 94-380).

In order for a claim such as this to be paid, it must be determined that death was medically caused by the vaccination. Based upon our review, we have concluded that this claim does not meet this criterion.

We have also considered this claim under the Federal Tort Claims Act (28 U.S.C. Section 2671 et seq.) which provides for claims against the United States only where the negligence of a federal employee is involved. However, since it does not appear that any such negligence caused the death on which your client's claim is based, the claim is also denied under that statute.

You may, if you disagree with this decision, file suit against the United States in the appropriate U.S. District Court within six (6) months after the date of this final denial of this claim.

Sincerely yours,

/s/ Sarah Hertz

SARAH HERTZ

Chief, Litigation and Claims

Branch

Business and Administrative Law

Division

Decision of the United States District Court for the Western District of Louisiana in the case of Mills v. United States, on the issue of causation

IN THE UNITED STATES DISTRICT COURT FOR

THE WESTERN DISTRICT OF LOUISIANA

MONROE DIVISION

CIVIL ACTION

NO. 78-1315

MRS. KATHLEEN N. MILLS AND

MICHAEL WAYNE MILLS

versus

UNITED STATES OF AMERICA

FOR PLAINTIFFS

EDGAR H. LANCASTER, JR.

LANCASTER, BAXTER & LANCASTER

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DEPARTMENT OF JUSTICE

WASHINGTON, D. C. 20530

NAUMAN S. SCOTT

CHIEF UNITED STATES DISTRICT JUDGE

O P I N I O N

Mrs. Kathleen N. Mills, individually and on behalf of her minor child, Michael Wayne Mills,[1] has sued the United States of America, alleging that the death of her husband, Wayne W. Mills, (sic) was caused by a swine flu vaccination administered under the National Swine Flu Immunization Program of 1976, 42 U.S.C. §§ 247(b)(j)-(l). We retain jurisdiction under that Act and the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2671, et seq. Upon stipulation by the parties, we bifurcated the trial to first consider causation - whether the injection of the swine flu vaccine caused Mr. Mills' death.

INTRODUCTION:[2]

The Swine Flu Act of 1976 was an attempt by the Federal Government to inoculate the entire adult population of the United States against the threat of a

swine flu epidemic. It was the largest immunization program in this country's history and over 45 million Americans - or one-third of the adult population - were vaccinated. The initial vaccination was on October 1, 1976; and the program was suspended on December 16, 1976. The program, for which $135 million dollars was initially appropriated by Congress, called for using both private and public health systems to achieve its goal of inoculating the entire adult population by the end of November, 1976. The November deadline was critical since the season of intense flu transmission in the United States is generally considered to be September thru March.

The Swine Flu Act became law on August 12, 1976 and was applicable to all swine flu inoculations administered after September 30, 1976. Important provisions of the Act include the following:

1. The Act creates a cause of action against the United States for any personal injury or wrongful death sustained as a result of the swine flu inoculation resulting from the act or omission of a program participant upon any theory of liability that would govern in an action against such program participant including negligence, strict liability in tort, and breach of warranty; 42 U.S.C. § 247b(k)(2)(A);

2. It makes that cause of action the exclusive remedy (42 U.S.C. §247b(k)(3)) and abolishes the cause of action against the vaccine manufacturer; and

3. It makes the procedures of the Federal Tort Claims Act applicable to suits brought pursuant to the Swine Flu Act (42 U.S.C. §247b(k)).

The program was prompted in part by the medical discovery in early February,

1976 at Fort Dix, New Jersey, of military servicemen having a new strain of influenza virus antigenically related to the virus prevalent during the 1918-19 swine flu pandemic. That pandemic was responsible for 20 million deaths worldwide, including 500,000 in the United States alone. Prior to 1930, the strain was the predominant cause of influenza in the United States. Since 1930, the virus had been limited to transmission among swine only with occasional transmission from swine to human, with no secondary person-to-person transmission.

In addition, the Swine Flu Act was prompted by the collapse of the commercial liability insurance market, both for vaccine manufacturers and other program participants. The cases of Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968), and Reyes v. Wyeth

Laboratories, Inc., 498 F.2d 1264 (5th Cir. 1973), which held a manufacturer of polio vaccine strictly liable in tort, greatly contributed to the insurance problem. For this reason, the Swine Flu Act provided that the exclusive remedy for injury caused by the vaccine would be against the United States. However, since the manufacturers could still insure themselves against negligence liability, they may be liable in a suit by the United States (42 U.S.C. §247b(k)(7)) if the United States is found to be liable on a negligence theory.

History has demonstrated that no swine flu epidemic occurred during the winter of 1976-77. As can be expected, however, many people who were inoculated also incurred some type of illness, injury or adverse medical condition in a period relative to the vaccination.

Lawsuits, such as the instant one, were filed throughout the country for illnesses allegedly resulting from the immunization. In addition, numerous administrative claims have been filed.

FINDINGS OF FACT:

Decedent, Warren Mills, was 55 years of age and married to Kathleen N. Mills. Six children were born of that marriage. Decedent was in apparent good health. According to Mrs. Mills and family physician, Dr. Henry S. Provine, decedent had no prior history of cardiovascular problems, allergies or any other major illnesses. (Plaintiffs' Exhibit 19). Described as having a muscular build, decedent engaged in work requiring strenuous labor.

Upon hearing about the Government's swine flu program, Mr. and Mrs. Mills decided to receive the inoculation,

available without charge at the Madison Parish Health Unit (Unit). They lunched together on October 21, 1976, then proceeded in separate vehicles to the Unit. Mrs. Mills described her husband's condition on that day as normal. This testimony was corroborated by others who observed decedent at the Unit that day: Wilmer R. Roper, a close friend also present to receive the vaccination; Dell Taylor, a neighbor serving as a volunteer registered nurse at the Unit; Lloyd Erwin, a personal friend who served as the Unit Administrator; and Gail Byrd, an acquaintance serving as a volunteer registered nurse at the Unit.

Mr. and Mrs. Mills were given literature to read about the inoculation program. They signed the registration forms and received their vaccinations. Without waiting, they left the building together, exchanged goodbyes and parted.

Decedent reached his truck first, got in and closed the door while Mrs. Mills continued to her car. Mr. Roper, just behind them, was approaching his vehicle parked next to the Mills' truck. He looked over and noticed that decedent was experiencing physical difficulties - his chest and stomach heaving, his head thrown back, his face ashen in color. During this time decedent was pulling and clutching his chest and neck area.

Roper called to Mrs. Mills, approached decedent and touched him, whereupon decedent fell over on the seat. Roper then ran to the Unit for help. Erwin and Byrd ran out, removed decedent from the truck and placed him on the ground. They described decedent's state as unconscious and tonic or rigid, with white or ashen complexion and clammy skin. They applied cardio-pulmonary resuscitation (CPR). Decedent began

breathing briefly with heartbeat and improved color. During this time, epinephrine, a cardiac stimulant and bronchial relaxant, was administered intravenously. Decedent may have breathed unassisted a second time.

Dr. Henri Wiebe, associated with the Unit's inoculation program on a standby basis for "any untoward occurrences", was contacted and arrived in an ambulance approximately 20 minutes after decedent's difficulties began. Decedent exhibited no vital signs at that point and was officially pronounced dead by Dr. Wiebe upon arrival at the hospital.

By all accounts, decedent's collapse occurred within 2 to 5 minutes after receiving the swine flu vaccine. He died during the brief interval prior to Dr. Wiebe's arrival.

Dr. Najeeb Klam performed an autopsy on decedent 18 hours after the time of

death and prepared an autopsy report. (Plaintiffs' Exhibit 20). Relying upon the autopsy results, the clinical or pre-death descriptions and their expertise, both parties' experts agreed that the immediate cause of decedent's death was a myocardial infarction or coronary occlusion.[3]

Plaintiffs contend that the vaccination brought about an anaphylactic[4] reaction so severe as to result in anaphylactic shock, causing acute hypotension[5] and respiratory insufficiency which in turn caused the heart failure.

The Government maintains that the irreversible cardiovascular collapse experienced by decedent was due to Sudden Unexpected Coronary Death Syndrome (SUCDS), a much more common, though puzzling, heart-related cause of death. Decedent's preexisting heart disease was

identified as a probable instigator of the SUCDS.

Plaintiffs presented the following medical experts:

1. Dr. Provine, who in addition to serving as the Mills' family physician, had treated patients for anaphylaxis;

2. Dr. Najeeb Klam, the forensic pathologist who performed the autopsy in this case and has treated patients for anaphylactic shock and has performed autopsies on anaphylactic shock victims;

3. Dr. Ralph Simpson, an expert in the field of cardiology and internal medicine who has also treated patients for anaphylactic shock; and

4. Dr. Ran Phillips, an expert in the field of cardiology and internal medicine.

The Government presented testimony in the form of segments from depositions of medical experts taken in conjunction

with the national multidistrict litigation. The deposition of Dr. Wiebe as a fact and expert witness was also submitted. The following medical experts testified on behalf of the Government at trial:

1. Dr. John W. King, an expert in the field of internal medicine, specializing in infectious diseases; and

2. Dr. Henry G. Hanley, an expert in the field of internal medicine who is employed as a Professor of Medicine at Louisiana State University.

The autopsy revealed very apparent edema[6] in the myocardium,[7] lungs and visceral organs (liver, spleen, intestinal tract), and microscopic edema in the trachea and broncus. Emphysema in the lungs was noted as was the presence of a few eosinophils.[8] Anaphylaxis was not listed as the cause of death, coronary occlusion was. At trial, Dr.

Klam offered the opinion that anaphylactic shock was the cause of death. He explained the apparent discrepancy.

A. An anatomic diagnosis are (sic) the findings both grossly and microscopically of changes in the various tissues of the body that are caused by the varying diseases. A clinical diagnosis is that diagnosis that is established from the observation of a living patient with the various signs and symptoms in ancilliary tests that may establish a diagnosis.

Q. When you render an autopsy report, which diagnosis are you rendering?

A. It is on a dead person, and therefore, it can only be an anatomic diagnosis.

Tr. at 138.

Q. Dr. Klam, did you form an opinion as to what actually was the latest cause of death; that is, what actually did he die of?

A. Speaking as a pathologist and going on the anatomic diagnosis, there is only one diagnosis I can make; that this man died of a coronary occlusion, with infarction, old and recent. However, this heart attack, or the cause of the heart attack, is in my mind most probably due to the fact that he had an anaphylactic shock, which in itself may precipitate coronary thrombosis.

Q. Now, Doctor, in your autopsy report did you mention the anaphylactic shock theory?

A. Anaphylaxis is a clinical diagnosis, and I felt that in this particular case I should refrain from making any comment.

Q. So, you--the diagnosis of anaphylactic shock then would be a clinical diagnosis?

A. It is a clinical diagnosis, yes.

Tr. at 145-146.

As Dr. Klam's testimony and autopsy report indicate, decedent had a preexisting coronary artery disease. The Government experts strongly emphasized this factor.

The medical literature and testimony offered by both parties generally conform in their descriptions of anaphylaxis. The hypersensitivity or hyperimmunity from which anaphylaxis arises originates with a previously introduced foreign protein to the blood stream. During the first contact with the foreign protein

there is no allergic reaction, but an inordinate number of antibodies develop which "over react" when that substance is reintroduced, causing anaphylaxis. The reaction may not occur the very next time the protein in introduced and the hyperimmunity may not arise the very first time the body comes in contact with the offending agent. Additionally, there are myriad sources of foreign proteins. Thus the major difficulty with anaphylaxis is in predicting which individuals may be susceptible to it.

Flu vaccines, including the swine flu serum given to decedent, contain foreign proteins in the form of antigens. The purpose of a flu vaccine is to stimulate the production of antibodies with the presence of antigens. The antibodies combat particular influenza viruses that may subsequently be contracted. These vaccines have been

known to cause hyperimmunity and anaphylaxis. In fact, Drs. King and Hanley acknowledged that vaccination programs such as the Swine Flu Program present a real danger of anaphylaxis. (Tr. at 315-316, 373).

Decedent received three flu vaccinations between October of 1962 and January of 1963. (Plaintiffs' Exhibit 19). Plaintiffs' experts indicated that those inoculations may well have been the source of decedent's hypersensitivity to the swine flu vaccine. The Government's experts concurred insofar as they recognized such injections as being a source of hypersensitivity and therefore, anaphylaxis.

It was generally undisputed that the pathology of acute hypotensive anaphylactic shock and SUCDS are very similar. This includes edematous changes in the heart, lungs and visceral organs,

respiratory dysfunction, circulatory collapse and inevitable coronary damage. Additionally, these two forms of shock develop rapidly, without warning and usually result in death.

The most striking element to this case is the brief timelapse between the vaccination and death. The relevant medical literature presented to the court and all the experts who testified except Dr. King acknowledged the importance of this factor. "(T)he hallmark of the anaphylactic reaction is the onset of some manifestation within seconds to minutes after the introduction of the antigen, generally by ingestion or injection." Ishizaka, Experimental Anaphylaxis and Reaginic Hypersensitivity, Immunilogical Diseases, Chapter 49, at 890 (Sampter, ed.) (1978). (Plaintiffs' Exhibit 22).

At the same time, we are mindful

that "(M)ere temporal relation between the onset of a disease and the vaccination is insufficient to establish legal causation. Each plaintiff has the burden of proving that the swine flu inoculation was the proximate cause of a claimed injury or medical condition." Bean v. United States, 533 F.Supp. 567, 572 (D. Colo. 1980).

Dr. King relied heavily upon the statistical probabilities of someone dying from SUCDS as opposed to the uncommon anaphylaxis. He further relied upon statistics culled from the swine flu inoculation program itself presented in Retailliau, et al, Illness After Influenza Vaccination Reported Through a Nationwide Surveillance System, 1976-1977, 3 American Journal of Epidemology 270 (No. 3, 1980). (Government Exhibit G7006).

Of over 49 million people subjected to the swine flu vaccine, only 11 cases

of anaphylaxis were reported, none fatal. Of that same group, 2,303 people died from what was labeled as SUCDS, according to Dr. King. (Tr. at 255-56).

Dr. King by no means ruled out the possibility that decedent's death was precipitated by the vaccine which caused an anaphylactic shock. "I think that the clinical data is wholly compatible with anaphylaxis or with acute myocardial infarction." (Tr. at 250). "I am in full agreement with those people who would say it is possible that (death from the vaccine) could occur. Absolutely." (Tr. at 261). "(A)s I look at this information, as I have stated before, that there is no way that anyone can tell us what really happened. We cannot know the truth in this case.... (E)ither Mr. Mills had a reaction from swine flu leading to his death, or he did not have a reaction. . .from swine flu leading to

his death. And in a mathematical and very accurate sense because we cannot know what was the true cause of Mr. Mills' death. We can only suppose." (Tr. at 254-255).

We again quote from the trial transcript for the basis of Dr. King's conclusion, elicited during direct examination.

> Q. Then it is crystal-clear the only temporal relationship that is supported by statistics would be that you would expect sudden unexpected coronary death to have occurred . . .
>
> A. That is the most probable by far. There are no reported deaths of anaphylaxis.
>
> Q. Out of --.
>
> A. 49,161,019 patients vaccinated.

Tr. at 262. (Emphasis ours).

Plaintiffs' experts testified that some of the specific clinical symptoms associated with allergies (itching, rashes, wheezing and sneezing) that might

otherwise differentiate anaphylaxis from coronary disease, cannot develop due to the swiftness and severity of hypotensive anaphylactic shock. Drs. King and Hanley noted this phenomenon as well. (Tr. at 246 and 369).

Though the presence of edema is common to both SUCDS and anaphylaxis, Dr. Phillips pointed out that edema from the latter results when blood seeps through the walls of the capillaries altered by the allergic reation, whereas the seepage is caused by an increase in pressure during a myocardial infarction. (Tr. at 217 et seq). Additionally, Dr. Phillips testified that the buildup of edema is much more rapid during anaphylactic shock than it is for a myocardial infarction.

The Government assigns importance to the fact that no edema of the larynx was noted by Dr. Klam in his autopsy report. Yet Dr. King, on direct examination,

explained that larngeal edema "would not be expected in the type (of anaphylactic shock) in which there was a sudden hypotension and death." (Tr. at 271). Dr. Klam examined the larynx and found no apparent edema. He pointed out that larngeal edema is not necessary to a diagnosis of anaphylactic shock and that edema will dissipate between the time of death and the autopsy. (Tr. at 150-151). Dr. King agreed. (Tr. 270-271). Thus the anatomical findings on edema are fully compatible with hypotensive anaphylactic shock.

The anatomical finding of "a few eosinophils" is not unusual generally speaking. However, as Dr. Klam stated, "(I)n cases of allergy the presence of eosinophils is very important." (Tr. at 153).

Dr. Hanley classified decedent as "an extremely high risk" patient due to

the extent and asymptomatic nature of his preexisting heart disease (Tr. at 358); that this condition made decedent more susceptible to the consequences of anaphylaxis than someone without heart disease. (Tr. at 372). Yet Dr. Hurst, whose deposition testimony was offered by the Government, states in his widely recognized text, The Book of the Heart, "Even in patients without apparent heart disease, sensitization by exogenous agents may result in acute anaphylaxis with primary cardiovascular manifestations. Myocardial abnormalities occur, independent of changes in coronary blood flow." (Plaintiffs' Exhibit 25; see Government Exhibit G-601 at 8).

Due to the similarities between anaphylaxis and myocardial infarction, the medical profession has appreciated the possibility for misdiagnosing the former for the latter. Dr. Hurst writes

"Anaphylactic reactions to an variety of drugs are often associated with profound hypotension and have precipitated myocardial infarction in patients with underlying coronary atherosclerosis. . . . (B)cause of these manifestations, anaphylaxis has occasionally been misdiagnosed as myocardial infarction with shock." (Plaintiffs' Exhibit 25). (Emphasis ours). And with regard to serum sickness generally, Dr. Hurst points out that "A variety of cardiovascular abnormalities are encountered . . . The changes may mimic myocardial infarction." Id.

Without a doubt, all of the essential factors necessary to identify anaphylactic shock are present. These factors taken together signal anaphylaxis, however rare. Patients who suffer SUCDS exhibit some clinical and anatomical reactions similar to patients

who have suffered anaphylactic shock. Curiously, of the two, anaphylactic shock proves less of a mystery to the medical profession. Whereas the screening of hyperimmune patients may prove difficult, flu vaccines are known to trigger anaphylaxis. By contrast, as Dr. Hanley testified, "We don't know what causes Sudden Cardiac Death." (Tr. at 361).

Aside from the statistical probabilities, on an individual basis the factors and biological changes that have been identified with anaphylaxis are more defined than those that accompany SUCDS. We find that the inoculation of decedent with the swine flu vaccine was the cause-in-fact of the profound anaphylactic shock and resulting myocardial infarction from which he died.

CONCLUSIONS OF LAW

Under the Federal Tort Claims Act,

which provides the jurisdictional basis for this suit, the law of the place where the alleged wrong occurred controls the action. 28 U.S.C. § 1346 (b). Louisiana law controls the determination as to burden of proof and legal or proximate cause.

Plaintiffs must prove by a preponderance of the evidence that the injury more probably than not was caused by an act attributable to the Government. Wright v. United States, 507 F.Supp. 147, 157 (E.D. La. 1981). "Causal relation is essentially a factual concept that requires a determination of whether the defendant's conduct was a substantial factor contributing to the plaintiff's harm. Andrus v. Trailers Unlimited, etc., 647 F.2d 556 (5th Cir. 1981)." Hidalgo v. United States, No. 79-1453 (W.D. La. Oct. 16, 1981), at 8.

In this case there is no direct

evidence to establish a causal relationship. However, causation may certainly be proved by circumstantial evidence. Lombard v. Sewerage & Water Board of New Orleans, 284 So.2d 905, 913 (La. 1973); Naquin v. Marquette Casualty Co., 153 So.2d 395, 397 (La. 1963).

It is possible that decedent experienced SUCDS, but the law in Louisiana does not require plaintiff to overcome such a factor.

> To meet the burden of proof required in civil cases, the circumstantial evidence need not negate all other possible causes, it need only prove the causal relationship be more probable than not. Further, the breach of duty need not be shown to be the sole cause of the injury; it is a cause - in fact of the harm to another if it was a substantial factor in bringing about or not preventing the harm that the duty was intended to protect against. Vonner v. State Dept. of Public Welfare, La., 273 So.2d 252, 255 (1973).

Thompson vs. United States, 368 F.Supp. 466, 469 (W.D. La. 1973) (citations

omitted); also quoted in Wright v. United States, supra, at 147.

The Government's experts were influenced by decedent's preexisting heart disease, the rarity of anaphylactic shock and the statistical probabilities as reported in the Retailliau article. Considering the potential for confusing anaphylactic shock with cardiac arrest, we question the accuracy of these statistics. If decedent's demise came about from having received the swine flu vaccine, then clearly one death from anaphylactic shock was not reported. Further, how many such deaths must there be before one can conclude that it is more probable than not that death was due to anaphylactic shock instead of SUCDS? Are we to assume that since anaphylaxis is the more rare of the two conditions, its occurrence may never prove statistically more probable than SUCDS, even following

an inoculation program?

We need not judge this case by medical certainty, only by a reasonable medical probability. Wright v. United States, supra, at 159. Whereas SUCDS may occur anywhere and anytime, hypotensive anaphylactic shock is known to occur only in previously sensitized patients immediately after inoculation of an antigen-laden serum, with results, both clinically and anatomically, such as those exhibited by decedent. Without hesitation, we find that the swine flu inoculation was the legal and proximate cause of decedent's death. It is so ordered.

THUS DONE AND SIGNED at Alexandria, Louisiana on this the 14th day of June, 1982.

/s/ Nauman S. Scott
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT

FOR

THE WESTERN DISTRICT OF LOUISIANA

MONROE DIVISION

MRS. KATHLEEN N. MILLS AND
MICHAEL WAYNE MILLS

VS CIVIL ACTION NO. 78-1315

UNITED STATES OF AMERICA

AMENDED AND SUPPLEMENTAL OPINION

The Court hereby amends and supplements its Opinion dated June 14, 1982 by omitting the last sentence of the first full paragraph on Page 15 and substituting the following in its stead: "Accepting the probability hypothesis of Drs. King and Hanley, no one has ever died of anaphylaxis. Even these witnesses cannot medically accept that conclusion."

DONE AND SIGNED at Alexandria, Louisiana, on this the 22nd day of June, 1982.

/s/ Nauman S. Scott
UNITED STATES DISTRICT JUDGE

1/

Since attaining majority he has been added as a party plaintiff by stipulation.

2/

We offer this introduction from Bean v. United States, 533 F.Supp. 567, 571 (D.C. Colo. 1980). Owing to its conciseness and clarity on the subject of the swine flu program it has been adopted verbatim in many other cases as well. Titchnell v. United States, No. 78-4083 (N.D. Iowa, Dec. 31, 1980); Barnes v. United States, 516 F.Supp. 1376 (W.D. Pa. 1981); Gicas v. United States, 508 F.Supp. 217 (E.D. Wis., 1981); Alvarez v. United States, 495 F.Supp. 1188 (D.C. Colo., 1980).

3/

A type of heart attack brought about by circulatory failure or loss of blood supply to the heart in association with thrombosis (blood clot); the infarction referring to the resulting death or necrosis of cardiac tissue.

4/

Anaphylaxis is an allergic reaction caused by a preexisting hyperimmunity to a particular foreign agent, usually protein based.

5/

A drop in blood pressure.

6/

A condition characterized by abnormally large amounts of fluid and swelling in bodily cavities and organs.

7/

The middle and thickest layer of the heart wall, composed of cardiac muscle.

8/

A type of cell found in the lungs and organ tissues and associated with allergies.

Decision of the United States District Court for the Western District of Louisiana in the case of Mills v. United States, on the issues of liability and quantum

IN THE UNITED STATES DISTRICT COURT FOR

THE WESTERN DIVISION OF LOUISIANA

MONROE DIVISION

CIVIL ACTION

NO. 78-1315

KATHLEEN N. MILLS, INDIVIDUALLY AND AS

NATURAL TUTRIX OF HER MINOR,

MICHAEL WAYNE MILLS

VERSUS

UNITED STATES OF AMERICA

FOR PLAINTIFFS:

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NAUMAN S. SCOTT

UNITED STATES DISTRICT JUDGE

O P I N I O N

Plaintiffs Kathleen Mills, and her son Michael Mills, have brought this action against the United States of America (the Government), alleging that the death of Wayne W. Mills (husband of plaintiff Kathleen Mills and father of Michael Mills) was caused by a swine flu vaccination administered under the National Swine Flu Immunization Program of 1976. See 42 U.S.C. §§ 247b(j)-(l). We bifurcated the trial to first consider causation -- whether the injection of the swine flu vaccine caused Mr. Mills' death. In our ruling of June 14, 1982, we found that the swine flu inoculation administered on October 21, 1976 was the legal and proximate cause of decedent's death a few minutes later.[1]

The issues now before us are: (1) Is the Government liable to the plaintiff

for the death of Mr. Mills; and, if so, (2) What is the amount of damages owed to plaintiff? For the reasons set forth herein, we find that the Government must compensate plaintiffs for Wayne Mills' death, and accordingly award plaintiffs total damages of $270,665.25.

I. LIABILITY

The Swine Flu Act creates a cause of action against the United States for any personal injury or wrongful death sustained as a result of the swine flu inoculation resulting from an act or omission of a program participant. Theories of liability that would govern in an action against such a program participant include negligence, strict liability in tort, and breach of warranty. 42 U.S.C. § 247b(k)(2)(A). It makes that cause of action the exclusive remedy, 42 U.S.C. § 247b(k)(3),

abolishing the cause of action against the vaccine manufacturer, and makes the procedures of the Federal Tort Claims Act (FTCA) applicable to suits brought pursuant to the Swine Flu Act. 42 U.S.C. x 247b(k).

Under the Federal Tort Claims Act, which provides the jurisdictional basis for this suit, the law of the place where the alleged wrong occurred controls this action. 28 U.S.C. § 1346(b). Mr. Mills was vaccinated at the Madison Parish Health Unit in Tallulah, Louisiana. Therefore, Louisiana law determines the burden of proof as to negligence,[2] products liability, and damages.

Louisiana has adopted a duty-risk approach to negligence cases. Hill v. Lundin & Associates, Inc., 260 La. 542, 256 So.2d 620 (1972). Under this approach, a plaintiff must show four elements in order to make out a

successful negligence cause of action:

1. A causal relationship between the defendant's conduct and the plaintiff's injury;

2. A duty owned by the defendant with respect to the plaintiff's injury;

3. That the defendant breached his duty with respect to the plaintiff, i.e., that the defendant was negligent;

4. Damages.

See Andrus v. Trailers Unlimited, Etc., 647 F.2d 556, 558-59 (5th Cir. 1981).

We will consider each element here.

A. Causation. Causation was determined against the Government - our Ruling of June 14, 1982.

B. The Government's Duty. The Government clearly had a duty to warn and inform potential vaccinees fully of the risks and benefits of receiving the swine flu vaccine pursuant to the Swine Flu Act and the Federal Tort Claims Act. Petty v. United States, supra, 536 F.Supp. §

247b(j)(1)(F) as the "development..... and the implementation of a written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each individual to whom such vaccine is to be administered." In plain language, the statute provides that vaccine recipients will also be advised with respect to their rights and remedies arising out of the administration of such vaccine.

C. The Government's Negligence. Mr. and Mrs. Mills had learned through Government-instituted newspaper and magazine articles, radio and television commercials, news programs, and a nationwide broadcast by President Ford, of the possibility of a swine flu epidemic and of the Government's vaccination program. Thus, Mr. and Mrs. Mills were persuaded to take the shots,

which were being offered for one day only at the Madison Parish Health Clinic. Neither Mr. Mills nor his wife were warned of a risk of anaphylactic shock. The first time that either of them were given any information about the vaccine was October 21, 1976 when they were handed two forms as they entered the clinic to receive their shots.

It is the Government's contention that these forms constitute the "informed consent form" required by Congressional Directive, 42 U.S.C. § 247b(j)(1)(F). The Government asserts that the forms not only inform Mr. Mills of the vaccine's "risks and benefits," but that Mr. Mills' signature on the "registration form" implicitly acted as a sort of waiver in regard to his "rights and remedies."

One of these documents (P. 17) is entitled "Important Information From the U. S. Public Health Service About Swine

Flu and Victoria Flu Vaccines." The pertinent portions of this read as follows:

"INTRODUCTION.

"You probably have heard a good deal about swine flu and swine flu vaccine. You may know, for example, that swine flu caused an outbreak of several hundred cases at Fort Dix, New Jersey, early in 1976 -- and that before then, swine flu had not caused outbreaks among people since the 1920s.

"With a vast majority of Americans being susceptible to swine flu, it is possible that there could be an epidemic this winter. No one can say for sure. However, if an epidemic were to break out, millions of people could get sick. Therefore, a special swine flu vaccine has been prepared and tested which should protect most people who receive it.

* * *

"The vaccines have been field-tested and shown to produce very few side effects. Some people who received the vaccine had fever and soreness during the first day or two after vaccination. These tests and past experience with other flu vaccines indicate that anything more severe than this would be highly unlikely.

(Then follows a paragraph about pregnancy).

"As indicated, some individuals will develop fever and soreness after vaccination. If you have more sever symptoms or if you have fever which lasts longer than a couple of days after vaccination, please consult your doctor or a health worker wherever you received medical care.

"While there is no reason to expect more serious reactions to this flu vaccination, persons who believe they have been injured by this vaccination may have a claim. (There follows information about where to file a claim).

"Attached is more information about flu and flu vaccine. Please take the time to read it carefully. You will be asked to sign a form indicating that you understand this information and that you consent to the vaccination."

The second document (which the Government refers to as an "informed consent form") is entitled "Important Information About Swine Influenza (Flu) Vaccine (Monovalent), dated July 15, 1976 (P. 15):

"The Disease.

"influenza (Flu) is caused by

viruses. When people get flu they may have fever, chills, headache, dry cough, or muscle aches. Illness may last several days or a well or more, and complete recovery is usual. However, complications may lead to pneumonia or death in some people. For the elderly and people with diabetes or heat, lung, or kidney diseases, flu may be especially serious.

"It is unlikely that you have adequate, natural protection against swine flu, since it has not caused widespread human outbreaks in 45 years.

"The Vaccine.

"The vaccine will not give you flu because it is made from killed viruses. Today's flu vaccines caused fewer side effects than those used in the past. In contrast with some other vaccines, flu vaccine can be taken safely during pregnancy.

"One shot will protect most people from swine flu during the next flu season; however, either a second shot or a different dosage may be required for persons under age 25. If you are under 25 and a notice regarding such information is not attached, this information will be provided to you wherever you receive the vaccine.

"Possible Vaccine Side Effects.

"Most people will have no side effects from the vaccine. However,

tenderness at the sight of the shot may occur and last for several days. some people will also have fever, chills, headache, or muscle aches within the first 48 hours.

"Special Precautions.

"As with any vaccine or drug, the possibility of severe or potentially fatal reactions exist. However, flu vaccine has rarely been associated with severe or fatal reactions. In some instances, people receiving vaccine have had allergic reactions. You should note very carefully the following precautions:

"(Relating to Children).

"People with known allergy to eggs should receive the vaccine only under special medical supervision.

"People with fever should delay getting vaccinated until the fever is gone.

"People who have received another type of vaccine in the past 14 days should consult a physician before taking the flu vaccine.

"If you have any questions about flu or flu vaccines, please ask.

"I have read the above statement about swine flu the vaccine, and the

special precautions. I have had an opportunity to ask questions, including questions regarding vaccination recommendations for persons under age 25, and understand the benefits and risks of flu vaccination. I request that it be given to me or to the person named below of whom I am the parent or guardian."
(There follows a place for the name, signature, and address of the vaccinee, his birthdate, and age. It was signed by Mr. Mills on October 21, 1976)."

Dr. King, an Infectious Disease Specialist who testified as the Government's expert on the kinds of warnings and information usually given to vaccine recipients in Louisiana, stated, "In fact, this type of informed consent far exceeds the informed consent generally given within programs of vaccination."

The Government argues that the risk of anaphylactic shock was not an occurrence that reasonably could be anticipated, citing statistics. The statistics are questionable (see our

ruling of June 14, 1982). However, a principal Government Witness, Dr. Michael A. Hattwick,[3] testified that he and his superiors expected the possibility of an anaphylactic reaction from the vaccine, including acute allergy or anaphylactic reaction occurring within an hour of the inoculation which could consist of hypotension and bronchospasm, and he expected the possibility of myocardial infarctions. This information was kept from the public because the Government feared that the disclosure of such facts might have deterred the public from taking the shot. In his Deposition at page 281, Dr. Hattwick stated:

> "Q. From your point of view what was the purpose of the form, what was your understanding of the purpose?
>
> "A. As far as my understanding it was a legal requirement in order o demonstrate that we had provided informed consent ...
>
> "Q. What was the purpose of this

registration form that people were to read before they got a shot?

"A. To inform them of the risks and benefits of the vaccination .... The primary purpose of the program was to make it available as it was to the opinion of the people who were running the program that the people should take it. It was in their best interest ....

"Q. So, any decisions that were made as to what to put on or off the consent form were decisions that were made --

"A. To encourage participation."

Dr. Jay Katz, a recognized expert in the field of consent who was involved in the preparation of the consent form, testified at trial by deposition. At pages 32-33 of his deposition, Dr. Katz was asked the following question:

"Q. ...In your opinion would someone reading the preceding information at the top of the page have a clear understanding of the benefits and risks of vaccination?

"A. No, they would not have. The signature is meaningless."

He also stated that it was "almost useless" to distribute the forms at the time the shots were given.

We conclude that the forms cannot be construed in any respect as being an informed consent. Plainly, important information about anaphylaxis and anaphylactic shock was left off the form because the framers feared that such information would deter people from taking the shot. The Government's argument that this information was intentionally omitted because the risk of anaphylaxis and anaphylactic shock was so small that it was not worth considering, is simply without merit. The question here is not whether the vaccine is generally beneficial to the public but whether each participant was well enough informed to intelligently ascertain the risk. Dr. King stated that it was as good as other warnings. Dr. Hattwick

recognized the possibility of an anaphylactic reaction but felt that a full explanation might discourage participation. Dr. Katz stated frankly that a signature, based on the disclosed information in the warning, was meaningless and was made "almost useless" by distributing the information at the time the shots were given. We agree with the court in Petty v. U. S., supra, at 864:

> "First of all it is called a 'registration form.' Nowhere do the words 'informed consent' or 'consent' appear. The individual is not advised with respect to his 'rights and remedies' which may arise out of the administration of the vaccine . . . .
>
> > "When Congress said to inform them of their 'rights and remedies', it must be assumed that it meant just that. This court cannot believe that Congress authorized the Secretary and the National Commission to withhold the fact that if they took the shot after signing the 'registration form' and then suffered personal injury or death, that

> they had no remedy. Congress said to tell them of their remedies, and this clearly implies that they must be told if they have no remedy.
>
> "Further, this court feels that it was misleading and much less than candid for the Government to imply to participants that you are 'registering' when they now argue to the court that what they really meant to tell participants, you are waiving your right to sue.'"

The participant, in this case Mr. Mills, could not have understood the benefits and risks of flu vaccine when he signed the "registration form". Nor does the form contain any language that the recipient assumed any risk or waived any remedy he might possess. This does not comply with 42 U.S.C. § 247b(j)(1)(F).

Louisiana provides by statute for the contents of consent form in La.R.S. 40:1299.40:

> "§1299.40 Consent to Medical Treatment.

"A. Notwithstanding any other law to the contrary, written consent to medical treatment means a consent in writing to any medical or surgical procedure or course of procedures which (a) sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadraplegia, paraplegia, the risk or loss of function of any organ or limb, of disfiguring scars associated with such procedure or procedures, (b) acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner, and (c) if signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent by a person who has legal authority to consent on behalf of such patient in such circumstances. Such consent shall be presumed to be valid and effective, in the absence of proof that execution of the consent was induced by misrepresentation of material facts.

"B. If such is provided in subsection A of this section, no evidence shall be admissible to modify or limit the authorization for performance of the procedure or procedures set forth in such written consent.

"C. Where the consent to medical treatment from a patient, or from a person authorized by law to consent

> to medical treatment for such patient, is secured other than in accordance with subsection A above, the explanation to the patient or to the person consenting for such patient shall include the matters set forth in ¶ (a) of subsection A above, and an opportunity shall be afforded for asking questions concerning the procedures to be performed which shall be answered in a satisfactory manner. Such consent shall be valid and effective and is subject to proof according to the rules of evidence in ordinary cases."

It is well established in Louisiana's jurisprudence that a patient (in this case, a vaccine recipient) must give an "informed consent," i.e., the physician [in this case, the Government] has a duty to disclose all known information material to a patient's intelligent decision to undergo a particular operation or therapeutic procedure." LaCaze v. Collier, 416 So.2d 619, 622 (La.App. 2nd Cir. 1982). The "material information" should include a description and explanation of the type

of medical procedure contemplated, the material risks involved and any alternatives available. Babin v. St. Paul Fire & Marine Ins. Co., 385 So.2d 849 (La.App. 1st Cir. 1980); Steele v. St. Paul Fire & Marine Ins. Co., 371 So.2d 843 (La.App. 3rd Cir. 1979); Percle v. St. Paul Fire & Marine Ins. Co., 349 So.2d 1289 (La.App. 1st Cir. 1977). While the statute does not require all conceivable risks incidental to vaccination to be disclosed, we have already established that anaphylaxis and anaphylactic shock were known, material risks associated with swine flu vaccination. They were clearly foreseeable risks that the Government did not disclose because it did not want to deter people from taking the shot. In addition to Dr. Hattwick's testimony, Dr. Joseph Bellanti testified that anaphylaxis was definitely a type of reaction to be

expected from a vaccination. Dr. John W. King, who testified in person during the first phase of this trial (as to causation), admitted that the occurrence of anaphylaxis following a swine flu vaccination was to be expected:

> "Q. And such as anaphylaxis?
>
> "A. Absolutely. That would be the one. The occurrence of anaphylaxis is really why you wish to have a physician with proper medical therapy there." (Trial Tr., Vol. III, p. 315).

We conclude that under both Federal and Louisiana State law, the Government had a duty to inform Mr. Mills of all material risks, including anaphylaxis and anaphylactic shock. The Government's failure to do so amounts to negligence.

Although the Government has a duty to protect the public from the ravages of disease, it also has a duty to fully inform citizens who volunteer for the vaccination of <u>all</u> the material,

potential risks. We find that the Government's forms were aimed at promoting the swine flu program rather than informing recipients of the risks involved. As such, the Government also has a duty to provide help and protection to citizen-recipients who develop illnesses and complications from their Government-sponsored vaccinations. The Government may not urge its citizens to undergo a potentially dangerous but preventive medical procedure, and then cloak its liability behind a complex and misleading registration form it now argues to be a consent form. The Government was negligent.

II. DAMAGES

At the time of his death, Mr. Mills was 55-years of age and had been married to Kathleen N. Mills (who was forty-nine) for thirty-three years. By all accounts,

the marriage was a happy, harmonious one. Of the couple's six children, only Michael W. Mills (a plaintiff in this action) was a minor, being 15 years of age when his father died. The evidence shows Mr. Mills to have been a hard worker -- he had been continuously self-employed as an automobile mechanic in a partnership with one Joe Reynolds -- and a good provider, devoted to his wife and family.

There is conflicting testimony concerning Mr. Mills' life expectancy. Plaintiffs assert that although Mr. Mills had a pre-existing heart condition,[4] with medication and possibly coronary bypass surgery, Mr. Mills could have had a normal and productive life expectancy. Dr. Jerry Hook plaintiff's economic expert witness, predicted that Mr. Mills would have lived 20.8 years and would have worked for 15 of those years.

Defendant contends that Mr. Mills had only a 50-50 chance of living 2 years. (Defendant's proposed Findings of Fact and Conclusions of Law, p. 7). Defendant's witness, Dr. Ran Phillips, stated in his deposition that, at the time he received the flu shot, "Mr. Mills was at risk of death at that time, and from the autopsy findings, had been at risk of death for many weeks, at least." However, Dr. Phillips allowed that this does not mean that Mr. Mills would not have lived had he in fact had a heart attack:

> "Q. Isn't it true that you would say that considering the vascular and heart condition of Mr. Mills that you are not in a position to say medically what his life expectancy would have been?
>
> "A. Not with any degree of -
>
> "Q. Medical certainty?
>
> "A. Degree of -- or assurance. But certainly there are people who have the degree of coronary

> artery disease that Mr. Mills had in that time frame and previous to that which have survived and are still living. But as to being definite in a manner of -- it is very difficult to be that definite in terms of any given human being." (Phillips' Deposition, p. 22).

Another medical expert, when asked whether Mr. Mills "could have died at any minute," agreed that although Mr. Mills was "a very likely candidate for a heart attack," he could not conclusively say that Mr. Mills would have died from such a heart attack. Mr. Mills, observed Dr. Simpson, "had been through heart attacks before in doing his work and he didn't die." Although Dr. Simpson admitted that, "a man with coronary disease . . . is less likely to have a long life than a man without it," he also said in reference to a similar case "if I had been talking with you about this patient that began his trouble back in 1958, I

wouldn't have thought he would be living twenty-five years from then."

After extensively reviewing the record, we find that plaintiffs have failed to meet their burden of proving that Mr. Mills' life expectancy was twenty-eight years as claimed. Plaintiffs' own medical experts were unable to render any opinion on this subject to any degree of medical certainty.[5] We must give credence the testimony of defendant's expert, Dr. Henry Garman Hanley, that it was likely Mr. Mills would have survived at least one year, and had a 50-50 chance of living for two years. However, it appears that this testimony did not completely take into account the fact that Mr. Mills was a particularly robust fifty-five year-old man who had manifested no symptoms of heart disease, had previously survived two heart

attacks, and engaged in strenuous activity up to the time of his death. He had an "easy-going disposition and no bad habits." (P-1). In view of Mr. Mills' physical strength and vigor, we find that Dr. Hanley's testimony somewhat underestimates his likely life expectancy. Although our estimate must necessarily be less than precise, we find it reasonable to believe that Mr. Mills' combined life expectancy and work life would have been five years.

For several years before his death, Mr. Mills' income had averaged approximately $9,000 a year. Based on Dr. Hood's calculations of base income, to which defendant has not directly objected, we find Mr. Mills' lost earnings for the end of 1976 through 1981 to total $61,843. Plaintiffs have also claimed damages for the loss of Mr. Mills' household services. Mr. Mills

built and maintained the family home himself, being skilled in plumbing, carpentry and electrical work. We find the loss of his household services for the same period to total $8,650.

Mrs. Mills seeks $150,000 and Michael Mills seeks $50,000 for loss of love, affection, companionship and society; these intangible elements of damages are concededly recoverable under Louisiana law, and defendant has not directly challenged plaintiffs' claims. We have commented previously on the close and devoted relationship between Mr. Mills and his wife. Mr. Mills was also an attentive father to Michael Mills, and the relationship between father and son was very close. The touching tribute paid to Mr. Mills in his son's high school year book emphasized the inspiration that he was to his family and community and the high esteem in which he

was held by those with whom he associated.[6] We do not find the damages sought here by plaintiffs to be excessive, and therefore award Mrs. Mills $150,000 and Michael Mills $50,000 in compensation for their loss.

The funeral bill was received in evidence, and demonstrates that plaintiff Kathleen Mills' out-of-pocket expenses for her husband's funeral totalled $172.25 (P-1). Mrs. Mills is entitled to compensation for this expenditure.

III. CONCLUSION

Based on the reasons discussed above, we grant judgment for plaintiffs and against the defendant as follows:

Mrs. Kathleen N. Mills:

For loss of love and affection - $150,000.00

For loss of support and earnings -	52,869.75
For funeral expenses	172.25
TOTAL	$203,042.00

Michael Wayne Mills

For loss of love and affection -	$ 50,000.00
For loss of support, care and education -	17,623.25
TOTAL	$ 67,623.25

IT IS SO ORDERED.

DONE AND SIGNED at Alexandria, Louisiana, on this 6th day of April, 1984.

/s/ Nauman S. Scott
UNITED STATES DISTRICT JUDGE

1/

The facts relevant to the instant opinion were fully set forth in our June 14, 1982 Opinion, and need not be repeated here.

2/

In view of this court's decision granting plaintiffs' relief on a negligence basis, there is no need to consider whether the Government is liable on the alternative theories advanced in the complaint.

3/

Dr. Hattwick is the Chief of Respiratory and Special Pathogens Branch, Viral Disease Division, Bureau of Epidemiology of the Center for Disease Control. He had been involved in the swine flu program by providing certain input into the consent form drafting committee. Dr. Hattwick testified about the consent form, and portions of the transcript of his deposition in the multidistrict litigation were introduced as P. 2-56.

4/

It was not known that Mr. Mills had coronary disease prior to his death; this was demonstrated at autopsy, which showed that he had had a heart attack in the past, a more recent heart attack, and that he had extensive coronary artery disease. (Testimony of Dr. Simpson, Tr., p. 9).

5/

Although the figure of 20.8 years was offered by plaintffs' economic expert, we cannot rely on this. Dr. Jerry Hood's expertise does not extend to

the field of medicine. On this subject, his lay opinion is insufficient to establish Mr. Mills' life expectancy.

6/

Mr. Mills was actively involved in all aspects of academic life at his son Michael's school. Not only was he involved in sporting events and other regular parental activities, but he used his mechanical and carpentry talents to repair school property, acting as a sort of volunteer handyman. The yearbook's obituary states:

> "The measure of a man is determined by the influence he exerts after his physical departure from this world. Certainly the Mills family is a LIVING memorial t the inspirational spirit of their father. Likewise his many endeavors in assisting his fellowman remain in the memories of all with whom he was associated. Mr. Mills was as much an integral part of Tallulah Academy - Delta Christian School as was any student or teacher. No task - large or small - was too unimportant for Mr. Mills to perform with precision and care. With deep feeling we can truly say with Shakespeare:
>
> > "His life was gentle, and all the elements So mixed in him that nature might stand up and say to all the world - This was a man!"

Mills v. United States
764 F.2d 373 (CA 5, 1985)

MRS. KATHLEEN N. MILLS, INDIVIDUALLY,

MICHAEL WAYNE MILLS, INDIVIDUALLY,

PLAINTIFFS-APPELLEES,

V.

UNITED STATES OF AMERICA,

DEFENDANT-APPELLANT.

NO. 84-4375.

UNITED STATES COURT OF APPEALS,

FIFTH CIRCUIT.

JULY 1, 1985.

Widow and son of deceased individual, who died from anaphylatic (sic) shock following swine flu vaccination, brought action against the Government pursuant to National Swine Flu Act. The United States District Court for the Western District of Louisiana, Nauman S. Scott, J., entered judgment in favor of plaintiffs, and Government appealed. The Court of Appeals, Jerre S. Williams, Circuit Judge, held that: (1) under Louisiana's uniform consent law, warning of risks of fatal or allergic reactions by Government adequately informed individual of risk of anaphylaxis; (2) even assuming that vaccine was an unreasonably dangerous product, in view of determination that Government's warning of possible allergic or severe reactions to the vaccine was adequate to inform individual of risk of anaphylatic (sic) shock, no breach of

duty on part of manufacturers was demonstrated for which Government could be held liable; and (3) there was no negligence on part of health care unit where vaccine was given.

Reversed and rendered.

1.DRUGS AND NARCOTICS-West key 17

By warning of risks of fatal or allergic reactions, Government adequately informed individual, under Louisiana's uniform consent law [LSA-R.S. 40:1299.40], of risk of "anaphylaxis," an acute, severe and sudden allergic reaction against a foreign protein or antigen that enters the body, and therefore was not liable as result of death of individual from anaphylatic (sic) shock following swine flu vaccination.

See publication Words and Phrases for other judicial constructions and definitions.

2. PRODUCTS LIABILITY-West key 5

In Louisiana, a manufacturer of a product which involves a risk of injury to the user is liable to any person, whether purchaser or third person, who without fault on his part, sustains an injury caused by a defect in design, composition or manufacture of an article, if the injury might reasonably have been anticipated.

3. PRODUCTS LIABILITY-West key 14

Manufacturer has an obligation to warn of any dangers inherent in a product's normal use which would not be within knowledge of ordinary user.

4. DRUGS AND NARCOTICS-West key 21

Even assuming that swine flu vaccine was an unreasonably dangerous product, in view of finding that Government's warning of possible allergic or severe reaction to vaccine was adequate to inform individual of risk of anaphylatic shock,

widow and son of deceased individual, who died from anaphylatic (sic) shock following swine flu vaccination, did not establish strict liability on part of the Government under Louisiana law.

5. HOSPITALS-West key 7

There was no proof that had doctor been on duty at health unit where swine flu vaccine was administered, he could have done more for individual, who died from anaphylatic (sic) shock following vaccination, than was done by unit operators, and therefore there was no negligence on part of the unit for failure to respond adequately to the shock for which the Government was liable.

Appeal from the United States District Court for the Western District of Louisiana.

Before WISDOM, WILLIAMS and HILL, Circuit Judges.

JERRE S. WILLIAMS, Circuit Judge:

I.

In August 1976, Congress enacted the National Swine Flu Act, 42 U.S.C. § 247b(j-1) (1976), in response to a perceived threat of a new strain of influenza virus. Initiation of an immunization program was in part prompted by the medical discovery in February 1977 (sic) of the swine flu virus in military servicemen at Fort Dix, New Jersey. The strain was related to the one that was prevalent during the 1918-19 swine flu pandemic that was responsible for 20 million deaths worldwide, including the deaths of 500,000 Americans. State, federal and local authorities, as well as private practitioners, took part in the Swine Flu Immunization Program initiated by the Federal Government. Under the

Swine Flu Act, the Federal Government accepted primary responsibility for injuries caused by the manufacture, distribution, or administration of the vaccine. Between October 1 and December 16, 1976, approximately one-third of the adult American population was vaccinated. Subsequent to the inoculations, numerous personal injury and wrongful death claims were filed.

This action was one such claim. Warren Mills and his wife, Kathleen N. Mills, decided to receive the swine flu inoculation. Mr. and Mrs. Mills had learned through Government-instituted newspaper and magazine articles, radio and television commercials, news programs, and a nationwide broadcast by President Ford, of the possibility of swine flu epidemic and the Government's vaccination program. On October 21, 1976, the Mills proceeded to the Madison

Parish Health Unit in Tallulah, Louisiana, where the vaccine was being administered free of charge.

Mr. Mills was given two documents to read concerning the swine flu vaccine just before he received the inoculation.[1] The first was entitled "Important Information from the U. S. Public Health Service about Swine Flu and Victoria Flu Vaccines: Introduction." This form provided very general information about the vaccine, informed vaccinees that persons who believed they had been injured by the inoculation might have a claim against the United States, and encouraged vaccinees to read carefully the other attached information. The last sentence of this form read, "You will be asked to sign a form indicating that you understand this information and that you consent to vaccination." The second document, entitled "Important Information

about Swine Influenza (Flu) Vaccine (Monovalent)", included the following warning:

> Possible Vaccine Side Effects
>
> Most people will have no side effects from the vaccine. However, tenderness at the site of the shot may occur and last for several days. Some people will also have fever, chills, headache, or muscle aches within the first 48 hours.
>
> Special Precautions
>
> As with any vaccine or drug the possibility of severe or potentially fatal reactions exists. however, flu vaccine has rarely been associated with severe or fatal reactions. In some instances people receiving vaccine have had allergic reactions.

Directly under the list of warnings was indicated "If you have any questions about flu or flu vaccine, please ask." The bottom third of the form was marked "Registration Form", and was signed by Mr. Mills.[2] He then received his vaccination.

Shortly afterwards, in the parking

lot of the Unit, Mills became ill. Help was sought at the Unit, and two members of the Unit's staff came out and administered cardio-pulmonary resuscitation. Mills was also given epinephrine by injection. He was taken to a hospital in an ambulance and was pronounced dead approximately twenty minutes after his physical difficulties began.

Mr. Mills was 55 years old at the time of his death and had no prior history of cardiovascular problems. An autopsy performed on the decedent 18 hours after his death indicated that the cause of death was a myocardial infarction or coronary occlusion.[3] Mr. Mills was subsequently determined to have suffered an extremely rare and severe allergic reaction to the vaccine known as anaphylactic shock. This allergic reaction produced the myocardial

infarction which resulted in Mr. Mills' death.

Mrs. Mills and her dependent son, Michael Wayne Mills, instituted administrative proceedings under the Federal Tort Claims Act. This procedure was required by the Swine Flu Act.[4] The Mills' claim was denied, and this action was then filed in the United States District Court for the Western District of Louisiana. Pursuant to an order of the Judicial Panel on Multidistrict Litigation (see 28 U.S.C. § 1407), the case was consolidated along with other swine flu cases for pretrial discovery and transferred to the Untied States District Court for the District of Columbia. Upon issuance of the final pretrial order, the action was remanded to the Western District of Louisiana.

A bifurcated trial was held by the district court. The first portion of the

trial considered only the question of causation. The district court found that the vaccination was the legal and proximate cause of Mr. Mills' death. The second portion of the trial addressed the issue of the Government's liability for Mr. Mills' death. It is this portion of the trial that is the subject of this appeal. In a non-jury trial, the district court found that the Government was negligent in that it had a duty to warn Mills of all material risks of the inoculation, including the risk of anaphylaxis, and that the Government's failure to do so resulted in Mr. Mills; death, for which the plaintiffs were awarded $270,000.

On appeal, we consider whether the Government had a duty to warn Mr. Mills of the risk of anaphylaxis and, if so, whether the Government adequately carried out that duty, raising the issue of

liability for negligence. We also consider whether the Government is liable for damages under a theory of strict liability. We reverse the district court and hold that the Government's warnings with respect to the risk of anaplylactic shock were sufficient and that the Government therefore is not liable for Mr. Mills' death under either a theory of negligence or under the warning requirement of Louisiana's law authorizing recovery based upon strict liability.

II.

The Swine Flu Act created a cause of action against the United States for any personal injury or wrongful death resulting from the swine flu inoculation. the United States was solely liable under the Act for the acts or omissions of program "participants", which included manufacturers, distributors, and

administrators of the vaccine. 42 U.S.C. § 247b(k)(3). Claims for damages could be premised upon "any theory of liability". 42 U.S.C. x 247b(k)(2)(A)(i). The procedures prescribed in the Federal Tort Claims Act ("FTCA") were made applicable to claims brought under the Swine Flu Act. 42 U.S.C. § 247b(k)(2)(A).

Under the FTCA, which provides the jurisdictional basis for this action, the "...law of the place where the act or omission occurred", is applicable for personal injury and wrongful death actions brought against the United States. 28 U.S.C. § 1346(b). Mr. Mills was vaccinated at the Madison Parish Health Unit in Tallulah, Louisiana. The issues of liability must therefore be determined under Louisiana law.

A. THE NEGLIGENCE CLAIM.

The district court's conclusion that the United States was liable for Mr. Mills' death was based on the theory that the Government's failure to warn Mr. Mills of the risk of anaphylactic shock was a breach of duty owned to the decedent. The district court, considering the adequacy of these warnings under Louisiana law,[5] found that the United States was negligent because the warnings fell short of the standards prescribed under Louisiana informed consent law. The court found that the Government had a duty to disclose all material risks involved in the administration of the vaccine, and that by failing to inform Mr. Mills of the risk of anaphylaxis, the Government had breached this duty. In so concluding, however, the court failed to consider the Louisiana Supreme Court's decision in

LaCaze v. Collier, 434 So.2d 1039 (La. 1983), in which the court specifically held that the materiality standard of informed consent had been superseded by Louisiana' Uniform Consent Law, La.Rev.Stat.Ann. 40:1299.40 (West 1977).

The Louisiana Uniform Consent Law, enacted in 1976, provides as follows:

> A. Notwithstanding any other law to the contrary, written consent to medical treatment means a consent in writing to any medical or surgical procedure or course of procedures which (a) sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, of disfiguring scars associated with such procedure or procedures (b) acknowledges that such disclosure of information has been made and that all procedures have been answered in a satisfactory manner, and (c) is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent by a person who has legal authority to consent on behalf of such patient in such circumstances. Such consent shall be presumed to be valid and effective, in the absence of proof that execution of the consent was

induced by misrepresentation of material facts.

B. Except as provided in Subsection A of this Section, no evidence shall be admissible to modify or limit the authorization for performance of the procedure or procedures set forth in such written consent.

C. Where consent to medical treatment from a patient, or from a person authorized by law to consent to medical treatment for such patient, is secured other than in accordance with Subsection A above, the explanation to the patient or to the person consenting for such patient shall include the matters set forth in Paragraph (a) of Subsection A above, and an opportunity shall be afforded for asking questions concerning the procedures to be performed which shall be answered in a satisfactory manner. Such consent shall be valid and effective and is subject to proof according to the rules of evidence in ordinary cases.

In LaCaze,[6] the defendant argued that the Uniform Consent Law merely intended to provide an evidentiary rule, and that if the procedures of the statute were followed, a presumption would be created that the consent of a patient was valid. The defendant argued that the

statute did not intend to affect the substantive law on informed consent. The court held, however, that the statute was more than a mere evidentiary rule and that it was intended by the legislature to redefine the jurisprudential rules relating to the disclosure requirement. The Court concluded that the statute was broader than the previous materiality standard with respect to required disclosure of risks inherent to a proposed treatment or procedure. The court in comparing the materiality standard with the statutory standard said:

> Under the materiality standard, both the severity of the consequence and the probability of occurrence are weighed by the physician; under the statutory rule, the consequences are listed, and the physician's requirement is to disclose all known risks of the listed consequences occurring, whether or not the probability of the occurrence is remote. No longer is the physician required to discuss with the patient alternatives to the proposed

> treatment. The "materiality" of the undisclosed risk, as such, need not be litigated.
>
> R.S. 40:1299.40, has therefore, superseded, in Louisiana, the jurisprudential rules defining "consent to medical treatment." A patient's consent to treatment must be measured by the standards contained in Subsection A or Subsection C of the statute.

Id at 1046. Under this standard, the question before us is whether the Uniform Consent Law required the Government to disclose the risk of anaphylaxis. According to LaCaze, failure to make disclosures required under the Uniform Consent Law constitutes a breach of duty on the part of the Government.

The Government argues that by warning of the risks of fatal or allergic reactions, it had adequately informed Mr. Mills of the risk of anaphylaxis under Louisiana law. We first note briefly the nature of the allergic reaction known as anaphylaxis. Anaphylactic shock is an

extremely rare and serious allergic reaction to any number of substances. It is an acute, severe and sudden allergic reaction against a foreign protein or antigen that enters the body. The agents of anaphylactic shock are many, including proteins, vitamins or chemicals. The shock can only occur in individuals who have had prior exposure to the particular substance that promotes the shock. The prior exposure "sensitizes" the individual to that substance. When the protein or antigen is reintroduced into the body, an aberrant attempt to eliminate the substance may result in anaphylactic shock. An individual may be exposed to a particular substance for years before manifesting signs of an anaphylactic reaction, as has been known to happen with penicillin. The shock can manifest itself in several ways, affecting the heart, respiratory system

or skin. Penicillin, anesthetics, peanuts, seafoods, and stinging insects are the most common and serious sources of anaphylactic producing agents.[7]

Mr. Mills had previously been exposed to a flu vaccine when he received a series of shots in 1962 and 1963. Although the vaccine was related to a different strain of flu, it was apparently closely enough related to sensitize Mr. Mills to the swine flu vaccine with the resulting anaphylactic shock and death.

The Government warning read and signed by Mr. Mills notified him that the swine flu vaccine could result in "allergic reactions" or in "severe or fatal reactions". Appellees argue that this warning was too vague to warn adequately of the risk of anaphylactic shock. Under the Louisiana Uniform Consent Law, known risks of death must be

disclosed. Anaphylaxis was a known, albeit rare, risk of death. Excluding Mr. Mills, 11 out of 49 million persons, or .00002 percent of those who received the swine flu vaccine, had an anaphylactic reaction to the serum. Not one of these other reported cases resulted in death; Mr. Mills is apparently the only fatality on record.

[1] We find that the Government warning that the swine flu vaccine could result in severe, fatal or allergic reactions complied with the Uniform Consent Law with respect to anaphylaxis. Although anaphylaxis was a known risk of death, Mr. Mills would not have been any better informed of the risks of the vaccine had he been told that a severe allergic reaction to a substance such as vaccine serum was called "anaphylaxis:. Furthermore, we do not feel that any greater detail of the pathology of

anaphylatic (sic) shock was required to put Mr. Mills on notice of the risk of this rare reaction. The Government could do no more than warn Mr. Mills that in receiving the vaccine, he could have a severe or fatal allergic reaction, as he or anyone could to any drug, injection or chemical substance. We therefore hold that the Government's warning was adequate to inform mr. Mills of the risk of suffering a fatally allergic reaction to the vaccine.

The district court, in concluding that the Government's warnings were insufficient, relied heavily on decisions from two other circuits where the same warnings were held to be inadequate. See Petty v. United States, 740 F.2d 1428 (8th Cir. 1984); Unthank v. United States, 7[illegible] F.2d 1517 (10th Cir. 1984). However, neither of those decisions reviewed the adequacy of the warnings

with respect to anaphylaxis. In Petty, the Eighth Circuit held that under Iowa law, the Government failed to warn the plaintiff adequately of the risk of serum sickness.[8] The plaintiff in that case suffered from inflamation and swelling of the joints from which he never fully recovered. Serum Sickness is a well-known and common disease resulting specifically from vaccine injections. The Eighth Circuit held the Government warnings to be inadequate because they failed to indicate in any way that such a disease was a possible risk of receiving the vaccine.

In Unthank, the Tenth Circuit held that the Government warnings were inadequate with reference to the condition of transverse myelitis suffered by the plaintiff in that case. The issue in Unthank was whether myelitis was a condition sufficiently linked to

Guillain-Barre Syndrome (GBS) to include the plaintiff's injuries in the class of cases for which the Government had already conceded liability. GBS is a neurological disorder suffered by many who received the swine flu inoculation. In response to the outbreak of GBS following the immunization program, the Secretary of Health, Education and Welfare declared that with respect to persons alleging GBS, the policy of the government would be to concede liability and provide compensation. The Tenth Circuit upheld the district court's finding that this concession of liability encompassed myelitis because it was closely enough related to the disorders produced by GBS.

The courts in both Petty and Unthank reached their respective conclusions based on the same analysis we have followed here. The question of the

adequacy of the warnings must be confined to consideration of whether the warnings were sufficient to inform the plaintiff of the risk of the particular condition or disease which allegedly caused his injury or death. Thus, our conclusion that the warnings were sufficient with respect to anaphylaxis has no bearing on whether those same warnings would adequately inform vaccinees of other risks such as serum sickness or myelitis. Similarly, a determination that warnings were inadequate with respect to some other condition does not bear on our conclusion that Mr. Mills was adequately informed of the risk of severe allergic reaction to the swine flu vaccine.

Under the Louisiana Informed Consent Law, we hold that the Government met the remaining requirements of Section 40:1299.30(A)(a) as well. There is no dispute that the disclosure was made in

writing, or that Mr. Mills signed the form indicating that he had been given the opportunity to ask questions concerning the risks involved in receiving the vaccine. Under the Informed Consent Law, a presumption of validity of the consent is created where there has been compliance with the statutory prerequisites. La.Rev.Stat.Ann. 40:1299.40(A). The plaintiffs here offer no evidence that would rebut the presumption that the consent was valid. Because the Government obtained Mr. Mills informed consent under Louisiana law, there was no breach of duty. The Government therefore is not liable for damages resulting from the death of Mr. Mills under the negligence theory.[9]

B. STRICT LIABILITY.

Appellees also urge that the Government is strictly liable for Mr.

Mills' death. 10/ The Swine Flu Act permits injured individuals to sue the Government based on any theory of liability, including strict liability. 42 U.S.C. § 247b(k)(2)(A). As with claims of negligence, the existence of strict liability must be determined with reference to the law of the state where the injury occurred.

[2] In Louisiana, a manufacturer of a product which involves a risk of injury to the user is liable to any person, whether purchaser or a third person, who without fault on his part, sustains an injury caused by a defect in design, composition or manufacture of an article, if the injury might reasonably have been anticipated. Hebert v. Brazzel, 403 So.2d 1242, 1244 (La. 1981); Weber v. Fidelity & Casualty Inc. Co. of N.Y., 259 La. 599, 250 So.2d 754, 755 (La. 1971). Under the Swine Flu Act, the United

States has assumed exclusive responsibility for any liability established on the part of a program participant in the administration of the swine flu vaccine. 42 U.S.C. § 247b(k)(2)(A). Hence, an injured individual alleging that the swine flu vaccine was defective has a cause of action exclusively against the Government.

[3, 4] Appellees do not allege that the vaccine itself was defectively manufactured, but argue that the swine flu inoculation was an unreasonably dangerous product, and that the manufacturer therefore had a duty to warn of that danger. A manufacturer has no obligation to warn of any dangers inherent in a product's normal use which would not be within the knowledge of an ordinary user. Hebert, 403 So.2d at 1245; Chappuis v. Sears Roebuck & Co.,

358 So.2d 926 (La. 1978), writ denied, 366 So.2d 576 (1979). Because the Government stands in the shoes of the manufacturer for purposes of liability under the Swine Flu Act, any liability for failure to warn of the risk of anaphylaxis is assumed by the Government. Even if it is assumed that the vaccine was an unreasonably dangerous product, we have already determined that the Government's warning of possible allergic or severe reactions to the swine flu vaccine was adequate to inform Mr. Mills of the risk of anaphylactic shock. Therefore, for purposes of establishing strict liability, the appellees have not demonstrated a breach of duty on the part of the manufacturers for which the Government could be held liable. Appellees are not entitled to damages on this theory.

C. NEGLIGENCE OF THE CLINIC.

[5] Finally, plaintiffs contend that the Government is liable for what they argue is the negligence of the Unit where the vaccine was administered. Plaintiffs allege that the Unit was not properly staffed because there was not a physician on duty at all times. Although no physician was on duty at the Unit, one was on call to respond to any emergencies arising from the administration of the vaccine. In fact, a physician did respond to a call placed in reference to Mr. Mills' condition.

There is no proof in the record that had a doctor been on duty at the Unit he could have done more for Mr. Mills than was done by the Unit operators. All of the medical literature admitted into evidence by the plaintiff indicates that the proper emergency response to anaphylaxis is to administer epinephrine. Cardio-pulmonary resuscitation (CPR) is

also advised. Mills was administered CPR and given an injection of epinephrine within minutes of his discovered difficulties. Therefore, we find no negligence on the part of the Unit for failure to respond adequately to Mr. Mills anaphylactic shock.

III.

Under Louisiana law, which is controlling in this action, we hold that Mr. Mills' consent to the swine flu vaccine was validly obtained and that there was no breach of duty on the part of the Government. Because we conclude that any question of liability against the Government turns on the adequacy of the warning given with respect to the risk of anaphylaxis, our determination that the warnings were sufficient compels the conclusion that the Government cannot be held liable for Mr. Mills' death on

either a theory of negligence or strict liability. Accordingly, we reverse the judgment in favor of appellees and direct that the district court render judgment that appellees take nothing in this suit.

REVERSED AND RENDERED.

1/

The Swine Flu Act called for the development of a written informed consent form and procedure "for assuring that the risk and benefits from the swine flu vaccine are fully explained to each individual to whom such vaccine is to be administered.... Such procedures shall include the information necessary to advice [sic] individuals with respect to their rights and remedies arising out of the administration of such vaccine." 42 U.S.C. § 247b(j)(1)(F). The two documents given to Mr. Mills were drafted in accordance with this provision.

2/

That part of the form provided, "I have read the above statement about swine flu, the vaccine, and the special precautions. I have had an opportunity to ask questions, including questions regarding vaccination recommendations for persons under age 25, and understand the benefits and risk of flu vaccination. I request that it be given to me or to the person named below of whom I am the parent or guardian."

3/

Myocardial infarction is a type of heart attack brought about by circulatory failure or loss of blood supply to the heart. Mr. Mills' reaction to the vaccine was compounded by the fact that Mr.

Mills was suffering from heart disease, which contributed to the myocardial infarction that resulted in heart failure. However, Mr. Mills' heart condition was unknown to him at the time he received the vaccine.

4/

The Swine Flu Act, 42 U.S.C. § 247b(k)(2)(A), provided that claims arising under the Act were governed by the procedures of the Federal Tort Claims Act. Under 28 U.S.C. § 2675(b) of the FTCA, an injured party had to present his claim to the appropriate administrative agency before filing an action in district court.

5/

We also note that the district court held that the warnings were inadequate under a federal standard of informed consent. The court construed 42 U.S.C. § 247(j)(1)(F) as creating a standard of informed consent as described under the Swine Flu Act. But this Court has previously held that no such nationwide standard of liability exists. Freeman v. United States, 704 F.2d 154, 157 (5th Cir. 1983). The mere directive that the Secretary of Health create an informed consent form and procedures did not establish a standard by which the sufficiency of the inform (sic) consent was to be evaluated. See also Daniels v. United States,

704 F.2d 587 (11th Cir. 1983); Petty v. United States, 679 F.2d 719 (8th Cir. 1979).

6/

LaCaze involved a malpractice suit brought by a woman who developed a vesico-vaginal fistula as a result of a hysterectomy. The fistula, which is an abnormal opening between two organs of the body, resulted from the possible nicking of the bladder while the physician was performing the hysterectomy, causing urine to flow out through the vagina. The physician in LaCaze failed to warn the patient of the risk of developing a fistula. See also infra, note 9, for further discussion of LaCaze.

7/

S. A. Kaplan, M.D., "Anaphyalaxis: (sic) Diagnosis, Prevention and Treatment", 13 Continuing Education 27 (July 1980).

8/

We note that Iowa has also enacted an Informed Consent Law that is nearly identical to the Consent Law adopted in Louisiana.

9/

We note that even if the warnings had been inadequate, appellees would not have been able to recover because they have not demonstrated that had Mr. Mills been warned more specifically of the risk of anaphylaxis, he would have foregone the vaccine. This causation element requires not only that the plaintiff show that the undisclosed risk was the cause of his injuries, but "the plaintiff must also prove that if the risk has been disclosed, the treatment and the unwanted consequences would have been avoided". (footnote omitted) LaCaze, 434 So.2d at 1048. The standard adopted by the LaCaze court to determine this causation issue is that of a reasonable person in the patient's position. In LaCaze, although the court did find that the doctor's notice to the plaintiff was inadequate, the plaintiff was barred from recovery because she had not met this burden of causation.

Mr. Mills was 55 years old at the time of his death. Although the autopsy indicated that he had rather severe atherosclerosis, he had never been diagnosed as having a heart-related condition. Post-program statistics confirm the failure of appellees to prove that if there had been full warning as to the specific danger of anaphylaxis Mr. Mills would have declined to be vaccinated. Out of 49 million vaccinations administered, there were only 11 other reported cases of anaphylaxis or, .00002 percent of

all vaccinees. None of these other instances resulted in death. Given the extremely rare incidence of anaphylactic shock, the plaintiffs have not demonstrated that a reasonable person would have foregone the vaccine had more specific information on anaphylaxis been provided.

10/

The district court granted relief on plaintiff's negligence claim only and did not reach the strict liability claim.

Denial of Rehearing by United States Court of Appeals, Fifth Circuit in the case of Mills v. United States

IN THE UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

MRS. KATHLEEN N. MILLS, Individually

MICHAEL WAYNE MILLS, Individually,

Plaintiffs-Appellees,

Versus

UNITED STATES OF AMERICA,

Defendant-Appellant.

- - - - - - - - - - -

Appeal from the United States District Court for the Western District of Louisiana

- - - - - - - - - - -

ON SUGGESTION FOR REHEARING EN BANC

(Opinion July 1, 1985, 5 Cir., 198_, _____F.2d_____)

(August 13, 1985)

Before WISDOM, WILLIAMS and HILL, Circuit Judges.

PER CURIAM:

(X) Treating the suggestion for rehearing en banc as a petition for panel rehearing, it is ordered that the petition for panel rehearing is DENIED. No member of the panel nor Judge in regular active service of this Court having requested that the Court be polled on rehearing en banc (Federal Rules of Appellate Procedure and Local Rule 35), the suggestion on Rehearing En Banc is DENIED.

( ) Treating the suggestion for rehearing en banc as a petition for panel rehearing, the petition for panel rehearing is DENIED. The judges in regular active service of this Court having been polled at the request of one of said judges and a majority of said judges not having voted in favor of it

(Federal Rules of Appellate Procedure and Local Rule 35), the suggestion for Rehearing En Banc is DENIED.

ENTERED FOR THE COURT:

/s/ J. S. Williams

United States Circuit Judge

CLERK'S NOTE:

SEE FRAP AND LOCAL RULES 41 FOR STAY OF THE MANDATE.

REHG-8

Unthank v. United States
533 F.S. 703 (D, Utah, 1982)

Verlin G. UNTHANK,

Plaintiff-Appellee

v.

UNITED STATES of America,

Defendant-Appellant,

No.82-2272.

United States Court of Appeals,

Tenth Circuit

May 1, 1984

Re-hearing Denied July 17, 1984

Action was instituted against the United States for damages sustained by plaintiff as a result of transverse myelitis subsequent to vaccination administered pursuant to the national swine flu immunization program. The United States District Court for the District of Utah, Sherman G. Finesilver, J., sitting by designation, 533 F. Supp. 703, entered

judgment for plaintiff, and the Government appealed. The Court of Appeals, McKay, Circuit Judge, held that: (1) District Court properly found that Landry-Guillain-Barre syndrome, for which concession of liability was made by the Secretary of Health and Human Services is a broad, encompassing term which would include the transverse myelitis suffered by plaintiff; (2) warnings were inadequate in cases such as transverse myelitis, which were known dangers at time time of program; and (3) since plaintiff was not adequately warned of attendant risks of taking swine flu vaccine and such a warning was called for by situation, product was unreasonably dangerous to plaintiff, and thus, having assumed the seller's liability, Government was

:rictly liable for injury caused to laintiff by injection of vaccine. ffirmed.

. Drugs and Narcotics 17

In action instituted against the nited States for damages sustained by laintiff as a result of transverse myeli- is incurred subsequent to vaccination dministered pursuant to national swine lu immunization program, district court roperly concluded that andry-Guillain-Barre syndrome, for which oncession of liability was made by ecretary of Health and Human Services, is broad, encompassing term which would nclude transverse myelitis suffered by laintiff. Public Health Service Act §§ 17, 317(j-1), (k)(2)(A)(i), as amended,

42 U.S.C. (1976 Ed.) §§ 247b, 247b(j-1), (k)(2)(A)(i).

2. Drugs and Narcotics 17

Warnings as to dangers of receiving swine flu immunization administered by United States were inadequate in cases such as transverse myelitis, which were known dangers at time of program. Public Health Service Act, §§ 317, 317(j-1), (k)(2)(A)(i), as amended, 42 U.S.C. (1976 Ed.) secs 247b 247b(j-1); (k)(2)(A)(i).

3. Physicians and Surgeons 15(8)

Under Utah law, relationship between a doctor and patient creates a duty on part of physician to disclose to patient any material information important to choosing a course of treatment, which includes duty to inform not only of risks that might occur from particular treatment

question, but also, any alternative treatments and risk of no treatment at all.

. Drugs and Narcotics 17

While Swine Flu Act adopts by reference law of jurisdictions in which cause of action arises, it is nonetheless the act itself which determines basis for that adoption and the question of whether those state laws should be construed narrowly or liberally. Public Health Service Act, §§ 317, 317(j-1), (k)(2)(A)(i), as amended, 42 U.S.C (1976 Ed.) §§ 247b, 247b(j-1), (k)(2)(A)(i).

. Drugs and Narcotics 17

In cases arising out of the Swine Flu Act, underlying state laws must be liberally construed in favor of claimants. Public Health Service Act, §§ 37,

317(j-1), (k)(2)(A)(i), as amended, 42 U.S.C. (1976 Ed.) §§ 247b(j-1), (k)(2)(A)(i).

6. Drugs and Narcotics 17

Legislative history showed a congressional intent to adopt strict liability for injuries arising from swine flu immunization program based on nothing more than a clearly supported finding that swine flu shots caused complained of injury. Public Health Service Act, §§ 317, 317(j-1), (k)(2)(A)(i), as amended, 42 U.S.C. (1976 Ed.) §§ 247b(j-1), (k)(2)(A)(i).

7. Drugs and Narcotics 17

Since plaintiff was not adequately warned of attendant risks of taking swine flu vaccine and such a warning was called for by situation, product was unreasonably dangerous to plaintiff, and thus, having

assumed seller's liability, Goverment was strictky liable for injury caused to plaintiff by injection or vaccine.

Before BARRET, McKAY and LOGAN, Circuit Judges.

McKAY, Circuit Judge.

This is one of many cases growing out of the now notorious national swine flu immunization Program of 1976, Pub.L. 94-380; 42 U.S.C. Sec. 247 b(j)-(1) (1976) (Swine Flu Act). As the record in this case, numerous other reported cases, and the legislative history indicate, Congress became concerned about a possible swine flu epidemic and, acting in a state of near emergency, passed the Swine Flu Act. The country was inundated with efforts urging people to go ahead with the swine flu vaccination program notwithstanding the reluctance of the drug

industry and insurance companies that esentially refused to proceed unless the United States Government assumed all liability that might arise from the vaccination program.

In that context, the plaintiff in this case under took the swine flu inoculation-program. At trial below, the trial court found that the Plaintiff contracted transverse myelitis as a direct and proximate result of the swine flu vaccination. The court also found that development of transverse myelitis as a proximate result of the swine flu inoculation was predictable under the state of the medical science in 1976, when this vaccine was administered to the Plaintiff. These fundamental findings are not challenged on appeal but in any event are abundantly supported by the record developed in this case. Again, on abundant

evidence, the trial court accepted the testimony that:

> Like [Guillain-Barre Syndrome (GBS)], many neuroglogist feel that transverse myelitis is an autoimmune reaction to an antigen challenge, resulting in the destruction of myelin in the nervous system. Although GBS involves the Peripheral nervous system and transverse myelitis the central, the mechanism by which demyelination occurs is which demyelination occurs is thought to be the same. (See generally Poser, M.D. L.Depo., pp. 20-30). It is logical to conclude that the time factor for demyelination in transverse myelitis is likewise similar. (footnote omitted).

UNTHANK v. United States, 533 F.Supp. 703, 714 (D.Utah 1982) (footnotes omitted).

reaction to an antigen challenge, resulting in the destruction of myelin in the nervous system. Although GBS involves the Peripheral nervous system and transverse myelitis the central, the mechanism by which demyelination occurs is which demyelination occurs is thought to be the same. (See generally Poser, M.D. L.Depo., pp. 20-30). It is logical to conclude that the time factor for demyelination in transverse myelitis is likewise similar. (footnote omitted).

UNTHANK v. United States, 533 F.Supp. 703, 714 (D.Utah 1982) (footnotes omitted).

The only question on appeal is the basis for liability. Plaintiff has alleged a variety of theories. While the trial court purported to reject several of

42 U.S.C. § 247b(k)(2)(A)(i). All three of the named theories are available under the law of the State of Utah where this vaccination was administered.

The trial court found on overwhelming evidence:

> With unparalleled haste, the bill came before the Senate on August 10, 1976, without hearings or a committee report, and was passed in amended form. 122 Cong. Rec. 26639 (August 10, 1976). The bill was sent to the House of Representatives, and even though many members had neither seen nor read the legislation, was expeditiously passed that same day. Id. at 26817. President Ford signed the National Swine Flu Immunization Program of 1976 into law on August 12, 1976.

Between October 1, 1976 and December 10, 1976 over 40 million Americans or one-third of the adult population of the United States--were vaccinated. This made the Swine Flu Act the largest vaccination program in history. In conjunction with the Swine Flu Act, the Department of Health, Education and Welfare conducted a surveillance program to evaluate illness temporally associated with influenza vaccination. By December 2, 1976, seven cases of GBS in two clusters had been reported. On December 16, 1976, based on data from four test states, the immunization program was suspended.

533 F.Supp. at 717.

Against this backdrop, the legislative history of the bill, whose precise language was not reviewed carefully by the individual members of Congress, becomes particularly important. Indeed, the Senate Appropriations Committee reported that "careful and indepth review (of the Swine Flu Act) was not possible." S.Rep. 94-1147, 94th Cong., 2d Sess. reprinted in 1976 U.S. Code Cong. & Ad.News 1987.

The trial court was particularly impressed, as we are, with the explicit statements of Senator Harrison A. Williams, Jr. of New Jersey in discussing the reasons for enacting this bill establishing liability against the federal government. He said:

> This is pioneering in the sense, it has never been done before, but it is in response to an emergency. That is the way the liability fixes upon the government, through the total class act, for any misfortune which would follow, as defined, the administration of the inoculation and vaccine .. 192 (sic) Cong. Rec. 26632 (August 10, 1976) (emphasis added).

533 F.Supp. at 719.

The trial court was also impressed, as we are, with the statement of Congressman Paul G. Rogers of Florida:

> [W]e have asked the drug companies to produce the vaccine. We have told them how to do it. We have told them the dosage we want, what strength. We gave them the

specifications because we are the only buyers, the Government of the United States. This is not the usual process of going out and selling. But if someone is hurt, we think people ought to have a remedy. [122 Cong.Rec. at] p. 26796 (emphasis added).

533 F.Supp. at 719.

The trial court also accurately noted that in response to the out break of GBS, then Secretary of Health, Education and Welfare, Joseph A. Califano, Jr., responded to the difficulities experienced after the administration of the program and the eruption of litigation. He declared that with respect to those alleging GBS, the policy of the government was to provide compensation to all who

contracted GBS from the swine flu vaccine. Secretary Califano stated that those who contract GBS:

> [W]ill not need to prove negligence by Federal workers or others in the Swine Flu Program as required by Federal law and the law in many states. Instead claimants in most cases need to show only that they in fact developed Guillain-Barre as a result of a Swine Flu vacination and suffered the alleged damage as a result of that condition. (Statement of Secretary of Califano, June 20, 1978).

533 F.Supp. at 718.

As the trial court noted, the Secretary gave two reasons for this policy:

First, the informed consent form .. did not warn individuals that there was a one in one hundred thousand risk that a person receiving a flu shot would contract Guillain-Barre and that one in every two million would die from the condition ... Second, in the Swine Flu program, the Federal Government, in an unprecedented effort, actively urged millions of Americans to get flu vaccination shots and funded the nationwide campaign. Thus we have decided to provide <u>just</u> _ <u>compensation</u> for those who contracted Guillain-Barre as a result of the Swine Flu program rather than force many individuals to prove government negligence in protracted proceedings. (Id) (Emphasis added).

533 F.Supp. at 718 (footnotes omitted).

[1] The Justice Department adopted the position of the Secretary for purposes of litigation. Based on this and other considerations, the trial court expressly held that Landry-Guillain-Barre Syndrome (GBS) is a broad, encompassing term which would include the transverse myelitis found in this case. Id. at 719. We believe record supports the trial court's conclusion. So long as it is proven to have been caused by the vaccination program, tranverse myelitis is included in the concession of liabiltiy made by the Secretary. Although the trial court said it did not ground its decision solely on the basis, id., we believe it is sufficient to support the trial court's determination.

In concluding that the Secretary was bound by his concession of liability, the court went on to give additional reasons for concluding that liability attached to the United States in this case. The trial court's additional findings and conclusions were, on their face, apparently meant to support its original conclusion that liability was grounded on a concession of liability in these cases falling broadly within the more generic understanding of the meaning of Landry-Guillain-Barre Syndrome. We believe those findings also support two other theories the court ostensibly rejected.

[2] First, even though the trial court expressly purported to reject a theory of inadequacy of the informed consent in this and in a previous case not appealed (Bean v. United States, 533 F.Supp. 567 (D.Colo. 1980)), we think its findings believe that conclusion. Thus, we conclude that the trial court's findings, as a matter of law, support the theory of inadequate informed consent. There is a split of authority among the trial courts[1] on this issue, but we beleive that those concluding that the warnings were inadequate together with the credited evidence in this case can lead to no other conclusion than the warnings were

inadequate in the cases such as transverse myelitis, which were known dangers at the time of the program.

[3] The doctrine of informed consent is a specialized form of negligence applied primarily in medical malpractice actions, which is essentially what this case is. Under Utah law, absent an emergency or unanticipated conditions, prior to treatment, a physician must inform the patient of all substantial and significant risks that might occur. Utah Code Ann. § 78-14-5 (1977); Reiser v. Lohner, 641 P.2d 93, 98 (Utah 1982). Further, the relationship between a doctor and patient creates a duty on the part of the physician to disclose to the patient any material information important to choosing a course of treatment. Nixdorf

v. Hicken, 612 P.2d 348, 354 (Utah 1980). We believe that encompassed in the duty to inform a patient of all material information, substantial and significant risks is the duty to inform not only of risks that might occur from the particular treatment in question, but also, any alternative treatments and the risk of no treatment at all.

[4,5] While the Swine Flu Act adopts by reference the laws of the jurisdictions in which the cause of action arises, it is nonetheless the act itself which determines the basis for that adoption and the question of whether those state laws should be construed narrowly or liberally. We believe that in cases arising out of the Swine Flu Act underlying state laws must be liberally construed in favor of

533 F.Supp. at 721.

Furthermore, the panic was unfounded. Id. at 717-18.

So monumental and effective were the urgings of the government that it resulted in an unprecedented nearly 40 million citizens responding to the call. Both this plaintiff and untold others relied on the government's assurances that the vaccine was both safe and necessary. A barrage of publicity aimed at overcoming the reluctance of citizens to participate included the unprecedented appearance of the President of the United States on national television to plead for a positive response. Against that background,iit would be a travesty to suggest that people who hurriedly signed the standardized form presented to them were adequately informed of the risks.

Even the Secretary conceded that the general language of the consent form was inadequate at least as to GBS. ID. at 718. In the face of the barrage of urgings from the authorities of the of the United States Government, it would defy logic and reason to suggest that an adequate warning was provided by the mere mention in the consent forms text that there was a "possibility of severe or potentially fatal reaction."Id. at 716. Perhaps in another context, such a generalized, uniformative statement might satisfy Utah and federal law, but we cannot conclude that in the factual setting in which this program and in which this planitiff specifically participated, that warning was "informed"for purposes of the act.

[6] Second, although the trial court concluded that the plaintiff did not prove strict liability, its analysis supports the conclusion that the legislative history shows an intent to adopt strict liability based on nothing more than a clear supported finding that the swine flu shots caused the complained of injury. In that connection the trial court put great emphasis on Congressman Rogers' statement that, "if someone is hurt, we think people ought to gave a remedy'' 122 Cong.Rec. 26796 (August 10, 1976), and on the statement of Senator Williams that, ''That is the way the liability fixes upon the government, through the total class act, for any misfortune that should follow, as defined, the administration of the inoculation

and vaccine ..." 122 Cong.Rec. 26632 (August 10, 1976) (emphasis added).

The trial court's further recitation of the congressional record and the milieu in which all of this took place supports the conclusion that the trial court's only real concern was about causation. The trial court correctly concluded that there was sufficient information prior to 1976 that a neurological disorder such as transverse myelitis was a recognized risk of influenza vaccination. 533 F.Supp. at 720. Tying that recognized fact to the statements in the congressional record, it is overwhelmingly clear that Congress intended people who suffered from these consequences to be compensated. It must be remembered that Congress acted in the face of the fact that the manufacturers

and the insurance carriers of all kinds so clearly recognized the risks that they were unwilling to proceed.

These recitations based on an adequate record are sufficient to support a cause of action based on "strict liability in tort'' expressly mentioned in the Swine Flu Act. 42 U.S.C. § 247b(k)(2)(A)(i). In Ernest W. Hahn, Inc. v. Armco Steel Co., 601 P.2d 152, 156 (Utah 1979), Utah adopted Restatement (Second) of Torts § 402A (1965), which reads as follows:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his Product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

The legislative history, as laid out by the trial court, clearly establishes that the United States Government intended

to assume the liability of the seller or manufacturer of the swine flu vaccine and that the vaccine reached the user without substantial change in the condition in which it was sold. Further, the evidence in the record supports a finding that even though the government may have exercised all possible care in the preparation and distribution of the swine flu vaccine, the plaintiff's injury was caused by the vaccine.

Thus, the only question left to be resolved is whether the product was "in a defective condition unreasonably dangerous to the user or consumer." Comment k of Restatement (Second) of Torts § 402A (1965) discusses unavoidably unsafe products, particularly in the context of vaccines or drugs. The comment notes that

even though many drugs and vaccines are incapable of being produced so that they will never cease injury, these drugs are not necessarily unreasonably dangerous.

Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.... The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the Public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A comment k (1965).

[7] Having already found that the plaintiff was not adequately warned of the attendant risks of taking the swine flu vaccine and that such a warning was called for by the situation, we find that under the standard set out in the Restatement, the product was "unreasonably dangerous" to the plaintiff. Thus, having assumed the seller's liability, the government is strictly liable to the injury caused to plaintiff by injection of the vaccine. For the reasons given, the judgment of the trial court is affirmed.

FOOTNOTES

1. Compare, e.g., Bean v. United States, 533 F.Supp. 567 (D.Colo.1980); Marneef v.United States, 533 F.Supp. 129 (E.D. Mich. 1981); and Warner v. United States, 522 F.Supp. 87 (M.D. Fla. 1981), with von Michalofski v. United States, No. C78-568R (W.D. Wash. Jan. 28, 1983); Petty v. United States, 536 F.Supp. 860 (N.D. Iowa 1980), reversed and remanded because wrong standard applied, 679 F.2d 719 (8th Cir. 1982); and Hasler v. United States, 517 F.Supp. 1262 (E.D. Mich. 1982), reversed on causation grounds, 718 F.2d 202 (6th Cir. 1983).

Petty v. United States
740 F.2d 1428 (CA 8, 1984)

Robert L. PETTY, Appellee,

v.

UNITED STATES of America, Appellant.

No. 83-1696.

United States Court of Appeals,

Eighth Circuit.

Submitted Dec. 13, 1983.

Decided Aug. 3, 1984.

Vaccine recipient filed suit against the United States for compensatory damages under the Swine Flu Act, in conjunction with the Federal Tort Claims Act. The United States District Court for the Northern District of Iowa, 536 F.Supp. 860, awarded recipient $212,802.22 in damages under negligence and strict liability theories. On appeal, the Court of Appeals, Bright, Circuit Judge, 679 F.2d

719, vacated the judgment and remanded the case with directions. On remand, the United States District Court for the Northern District of Iowa, Donald E. O'Brien, Jr., 592 F. Supp. 687 reinstated the damages award, and the Government appealed. The Court of Appeals, Lay, Chief Judge, held that: (1) the Government was liable under a negligence theory under Iowa law to recipient for the injuries he sustained as a result of his swine flu inoculation, and (2) the Government, under the Swine Flu Act, was derivatively liable for vaccine manufacturer's liability under a theory of strict liability.

Affirmed.

Bright, Circuit Judge, dissented and filed an opinion.

1. Negligence 10

Under Iowa law, the duty to warn in a foreseeablity negligence action is triggered by the reasonable foreseeability of the particular injuries sustained.

2. Federal Civil Procedure 2251, 2284

In a case tried to the court without a jury, the district court sits as the exclusive finder of fact; the district court has the task of resolving conflicts in the evidence by appraising credibility, weighing the evidence, and drawing inferences.

3. Evidence 571(3)

In suit filed against the United States for compensatory damages under the Swine Flu Act, medical testimony supported district court's finding that serum sickness and its symptoms were a

recognized reaction to the swine flu vaccination and, thus, that the Government was under a duty to warn vaccine recipients of the risk of serum sickness. 28 U.S.C.A. §§ 1346(b), 2671-2680; Public Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

4. Physicians and Surgeons 15(8)

Iowa informed consent statute does not allow risks of a medical procedure to be stated with the same generality applicable to the procedure itself. I.C.A. § 147.137.

5. Drugs and Narcotics 17

Without determining the applicability of the Iowa informed consent statute to suit against the United States for compensatory damages under the Swine Flu Act, prerequisites of the Iowa statute to the

creation of a presumption of informed consent were not satisfied, since the generality of the warning was insufficient to encompass the specific risk of serum sickness. I.C.A. § 147.137; 28 U.S.C.A §§ 1346(b), 2671-2680; Public Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

6. Drugs and Narcotics 17

In suit against the United States for compensatory damages under the Swine Flu Act, Iowa law mandated that the adequacy of the government's warning as to the risks involved in the swine flu vaccination procedure be assessed under the patient rule standard. 28 U.S.C.A § 1346(b), 2671-2680; Public Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

7. Physicians and Surgeons 15(15)

Under the Iowa patient rule standard, an individual must be advised of the inherent and Potential hazards of the proposed treatment, any alternative methods of treatment, the risk attendant to such alternatives, and the likely results of remaining untreated.

8. Physicians and Surgeons 15(8)

Under the Iowa patient rule standard, duty to disclose is limited not only to reasonably foreseeable risks but also to material risks.

9. Drugs and Narcotics 17

Under the Iowa patient rule standard, risk of serum sickness and its symptoms should have been disclosed to recipients of the swine flu vaccination. 28 U.S.C.A. §§ 1346(b), 2671-2680; Public

Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

10. Drugs and Narcotics 17

Iowa patient rule standard required the disclosure to swine flu vaccination recipients of the physiological source of possible reactions to the vaccination, likely results of foregoing the vaccination, or alternative methods of protection and risks attendant thereto in order for the Government to have obtained informed consent from the recipients of the vaccination. 28 U.S.C.A §§ 1346(b), 2671-2680; Public Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

11. Drugs and Narcotics 17

Vagueness of warning to recipients of swine flu vaccination of "severe or

potentially fatal reactions" was not mitigated by the invitation to receipients to ask questions, since the warning was insufficient to spark concerns that would have engendered questions, and it was unrealistic to believe anonymity of a mass immunization context would have fostered an atmosphere in which questions were likely to be asked or answered thoroughly. 28 U.C.A. §§ 1346(b), 2671-1680; Public Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

12. Drugs and Narcotics 17

Warning, which did not encompass the specific, known, and material risk of serum sickness and symptoms, did not provide an adequate basis under Iowa law for swine flu vaccine recipient to make an intelligent, informed consent and, thus,

did not discharge Government from its duty to warn recipient of the risks involved with receiving the vaccine. 28 U.S.C.A. §§ 1346(b), 2671-2680; Public Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

13. Drugs and Narcotics 17

To recover compensatory damages from the United States, swine flu vaccine recipient, under Iowa law, had to establish a causal relationship between the Government's failure to disclose the risks involved with the vaccine and and the injuries recipient sustained; causal relationship would exist if it could be shown that receipent would have foregone the vaccine had he been warned appropriately. 28 U.S.C.A. §§ 1346(b), 2671-2680; Public Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

14. Drugs and Narcotics 21

District court, in a suit against the United States to recover damages under the Swine Flu Act, properly applied a rebuttable presumption to the proximate cause issue by presuming that swine flu vaccine recipient would have acted to minimize the risk of serum sickness and its symptoms had been adequately warned, since the vaccine was given in a mass immunization context, public policy favored allocating the risk of loss among distributors, and "hard-sell" public relations campaign pursued by the Government not only encouraged participation but also greatly minimized the impact of the warning. 28 U.S.C.A. §§ 1346(b), 2671-2680; Public Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

15. Drugs and Narcotics 21

Finding was not clearly erroneous, in suit against the United States to recover compensatory damages under the Swine Flu Act, that Government did not rebut presumption that swine flu vaccine recipient would have acted to minimize the risk of serum sickness and its symptons had he been adequately warned, since district court apparently found recipient's testimony that he would have found more information helpful, more persuasive than the testimony cited by the Government. Fed. Rules Civ.Proc.Rule 52(a), 28 U.S.C.A; 28 U.S.C.A. §§ 1346(b), 2671-2680; Public Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

16. United States 78(12)

Actions of the President of the United States in attempting to encourage citizens to receive swine flu vaccinations were not within the discretionary function exemption to the Federal Tort Claims Act so as to preclude liability of the United States on negligence theory in action for injuries sustained as result of swine flu inoculation. 28 U.S.C.A. §§ 1346(b), 2671-2680, 2680(a); Public Health Service Act, § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

17. Drugs and Narcotics 18

Iowa law imposes a duty to warn on a drug manufacturer that extends to the ultimate consumer in a mass immunization case.

18. Drugs and Narcotics 18

Under Iowa law, a drug manufacturer is strictly liable for the breach of its duty to warn that extends to the ultimate consumer in a mass immunization case.

19. Drugs and Narcotics

Attempt by the Government to statutorily assume the duty of drug manufacturer to warn swine flu vaccinees did not relieve the manufacturer from liability for any resulting inadequacy of the warning under Iowa law; the duty to warn was imposed on the manufacturer and in a mass immunization context, in which there was no learned intermediary, the duty to warn extended to the ultimate recipient of the vaccine. 28 U.S.C.A. §§ 1346(b), 2671-2680, 2680(a); Public Heath Service Act, § 317 (j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

20. Products Liability 5, 6

Under Iowa law, negligence liability focuses on whether the manufacturer knew or should have known of some foreseeable harm arising from the use of its product; in contrast, a strict liability action focuses not on the manufacturer's conduct or knowledge but on whether the product, as marketed, is defective.

21. Drugs and Narcotics 17

Under Iowa law, drug manufacturer would have been strictly liable for its distribution of swine flu vaccine which was unreasonably dangerous due to an inadequate warning that did not appraise vaccine recipient of the known risk of serum sickness and symptons and which proximately caused recipient's injuries; thus, the United States, under the Swine Flu

Act, was derivatively liable for manufacturer's liability. 28 U.S.C.A. §§ 1346(b), 2671-2680, 2680(a); Public Health Service Act, § 317(2)(A)(i) as amended, 42 U.S.C.A. § 247(2)(A)(i); § 317(j-1), 42 U.S.C. (1976 Ed.) § 247b(j-1).

22. Drugs and Narcotics 17

Fact that the United States was derivatively liable for drug manufacturer's strict liability for swine flu vaccine recipient's injuries did not defeat the congressional intent of the Swine Flu Act to immunize drug manufacturers from unlimited liability exposure; by virtue of the liability scheme presented in the Act, the burden of both defending recipient's action and the resulting compensatory damages was borne by the United States. Public Health

Service Act, § 317(2)(A)(i), as amended, 42 U.S.C.A. § 247b(2)(A)(i).

Before LAY, Chief Judge, FLOYD R. GIBSON, Senior Circuit Judge, and BRIGHT, Circuit Judge.

LAY, Chief Judge.

Robert L. Petty filed suit against the United States for compensation damages under the Swin Flu Act, 42 U.S.C. § 247b(j-1) (1976), in con-junction with the Federal Tort Claims Act 28 U.S.C. §§ 1346(b), 2671-80. The district court, the Honorable Donald E. O'Brien presiding, found the United States liable under negligence and strict liability theories. Petty was awarded $212,802.22 in damages. Petty v. United States, 536 F.Supp. 860 (N.D. Iowa 1980). The

judgment was vacated on appeal and the case remanded to the district court with district court with directions to make express determinations of the government's liability under Iowa law. Petty v. United States, 679 F.2d 719 (8th Cir. 1982). On remand, the district court found the United States liable under Iowa law on negligence and strict liability theories for failing to provide Petty with an adequate warning of the known risks of the swine flu vaccination and reinstated the damages award Petty v. United States, 592 F.Supp. 687,No. C78 4083 (N.D.Iowa March 31, 1983). This appeal followed.

On appeal, the government contends that the district court's findings were clearly erroneous in that: (1) the risk of developing serum sickness was not reaso-

nably foreseeable at the time the vaccine was administered; therefore no duty to warn arose under Iowa law; (2) if such a duty arose, the warning given was not inadequate under Iowa law; and (3) if the warning was inadequate, the lack of adequate warning was not the proximate cause of Petty's illness. The government also appeals from the district court's decision holding the drug manufacturer strictly liable. Our prior opinion affirmed the trial court's finding that the swine flu shot did in fact cause Petty's injuries. 679 F.2d 729. This finding is the law of the case and is not challenged on appeal.

Petty received the swine flu shot on October 31, 1976, pursuant to the National Swine Flu Immunization Program,[1] at a vaccination center operated by the Sioux

City-Woodbury County Health Department, under the direction of the Iowa State Health Department. Prior to the inoculation, Petty received and "skimmed'' a form that related information about swine flu, possible side effects of the vaccine and Special Precautions. Reprinted infra p. 6-7. On November 8, 1976, Petty began to experience aching, numbness, and tingling sensations in his muscles and joints. His condition deteriorated and he was hospitalized on November 12, 1976. An initial diagnosis of congestive heart failure was changed to serum sickness. At the time of the original trial, Petty still epxerienced aching joints and a persistent

lack of strength. He has since recovered about 75% of his prior effectiveness.

Foreseeability

[1] Under Iowa law, the duty to warn in a negligence action is triggered by the "reasonable foreseeability" of the particular injury sustained. See, e.g., Lakatosh v. Diamond Alkali Co., 208 N.W. 2d 910, 913 (Iowa 1973); Davis v. Coates, Co., 255 Iowa 13, 19, 119 N.W. 2d 198, 202 (1963). Our prior opinion made it clear that finding ''an undifferentiated duty" to warn of the risks and benefits of receiving the swine flu vaccine was insufficent to establish the government's liability for failure to warn specifically of serum sickness. 679 F.2d at 728. The question remanded was whether serum sickness and its symptoms were reasonably

foreseeable and, if so, whether the goverment adequately warned of the risk.

The district court on remand found that "[t]he facts of this case clearly show that the dangers of serum sickness and abortive neuropathy from flu vaccines were well known in the medical community for a number of years prior to 1976." Slip op. at ____.[2] The court based its finding on the testimony of Dr. Clark Hyden, Dr. Joseph Bellanti, Dr. Charles Poser, and Dr. Hattwick.

Upon review of the reocrd, we find that the testimony supports the district court's conclusion that serum sickness and its symptons were a recognized reaction to the Swine Flu vaccination. Serum sickness was defined by Dr. Hyden, Petty's treating physician, as being ''a

Type 3 hypersensitivity reaction in which a foreign Protein is ingested or injected, which evidently sets up an antigen-antibody reaction, which in turn activates certain proteins which produce an inflammatory reaction throughout the body. This is called antigen excess disease or immune complex disease." Tr. at 115-16. Dr. Hyden testified that serum sickness was a disease of long standing well known in the medical literature caused when a foreign protein, such as in the vaccine here, is injected into the body. Dr. Bellanti, an immunologist and Director of the Center for Interdisciplinary Study of Immunology, similarly defined serum sickness as an antigen-antibody complex that results in redness, inflammation and swelling of the joints. This generalized

disease was named serum sickness in the days when horse serum was used to treat infectious diseases. Although serum is not used often anymore, Dr. Bellanti testified that the same reaction--a serum sickness like disease--is one of the recognized reactions to a vaccination.

[2, 3] In a case tried to the court without a jury, the court sits as the exclusive finder of fact. The district court has the task of resolving conflicts in the evidence by appraising credibility, weighing the evidence, and drawing inferences. Although a different trier of fact may have found differently, we conclude that on the basis of the testimony presented there was substantial evidence to support the district court's finding that serum sickness and

its symptoms were foreseeable. We cannot say that the court's finding reflects that a clear mistake has been made. Fed.R.Civ.P. 52(a). Accordingly, we affirm the district court's finding that the government was under a duty to warn vaccine recipients of the risk of serum sickness.

Adequacy of the Warning

Finding that the risk of serum sickness was reasonably foreseeable, we move now to the second issue raised on appeal, to wit, whether the government's warning[3] was inadequate under Iowa law to warn the plaintiff. To determine the adequacy of the warning, the district court relied on Iowa law:

> A duty to warn depends on superior knowledge and is said to exist when

> one may reasonably foresee danger of injury or damage to one less knowledgeable unless adequate warning of danger is given. It is this reasonable foreseeability which triggers the obligation to warn, which must be determined by the circumstances of each case.

Slip Op. at ___ (quoting Lakatosh v. Diamond Alkali Co., 208 N.W. 2d 910, 913 (Iowa 1973). Having determined that the risk of serum sickness was reasonably foreseeable, thereby triggering the duty to warn, the court then assessed the adequacy of the warning under the Iowa law.

Although "seriously questioning "the applicability of Iowa's Informed Consent Statute, Iowa Code § 147.137 (1975),[4] the district court found that the statutory

prerequisites to a presumption of informed consent were not satisfied; therefore, the statutory presumption could not alleviate the government's liability. The court primarly relied on the lack of specificity of the warning:

> The consent form given to the plaintiff failed to set forth the known risk of loss of function of any organ or limb. This symptom of serum sickness is one major element of plaintiff's damages. Thus, the Iowa informed consent law could not relieve the defendant of its liability for failure to warn of known dangers.

Slip op at --- Petty clearly sustained disabilities such as those described in section 147:137(1). In particular, Petty's symptoms included inflammation of the heart (an organ) and of the heart

muscle causing an impairment of function and endangering his life. The warning, however, makes no specific mention of this risk.

[4, 5] The government contends that the statute requires risks to be set forth only "in general terms," and that the warning's reference to severe or potentially fatal reactions" satisfies that requirement. We must respectfully disagree. First, the statute mandates that the presumption of informed consent arises if the writing "sets forth in general terms the nature and purpose of the procedure ... together with the known risks ....'' It is not at all clear that the generality allowed for description of the procedure also applies to the description of the risks. In light of the

specificity of the statutory language detailing certain risks, we find that the statute does not allow risks to be stated with the same generality applicable to the procedure. Second, even assuming that it did, for the same reasons discussed below, we find that the generality of the warning was insufficient to encompass the specific risk of serum sickness. Thus, without determining the applicability of the statute,[5] we affirm the district court's conclusion that the prerequisites to the statutory creation of a presumption of informed consent were not satisfied.

The government contends that the reference to "severe or potentially fatal reactions," coupled with the directive to ask questions is adequate under

Iowa law to discharge its duty to warn. The government contends that the risk of death encompasses lesser risks such that inclusion of a more specific risk would not have enlightened recipients or affected their decision to be incoulated. Some district courts have made finding that the government's warning was reasonable.[6] However, in this case we are presented with findings made by a different trier of fact on an obviously different record, and applying the law of Iowa. To be sure, there is a logical symmetry to the argument that acceptance of the risk of death implies acceptance of the risk of something less extreme. Judge O'Brien, however, made a finding to the contrary. Slip op. at ---. The only circuit court to have passed on this question affirmed a

finding of inadequacy, in accordance with Judge O'Brien's rationale. Unthank v. United States, 732 F.2d 1517 (10th Cir. 1984). In Unthank the Tenth Circuit held that a warning identical to that given Petty was inadequate as a matter of law to apprise the plaintiff of the known risk of transverse myelitis. See also Hasler v. United States, 517 F. Supp. 1262, 1268 (E.D. Mich. 1981), rev'd on causation grounds, 718 F.2d 202 (6th Cir. 1983) (warnings given to the plaintiff were minimal and so bland that no reasonable person would consider him or herself to be in any danger whatever from taking the drug); Claxton v. United States, No.EP-78-CA-142 (W.D. Tex. May 31, 1983) (warning was wholly inadequate to inform a reasonable, prudent person of the known

risk of severe neurological complications and was misleading in that it was presented as more of a disclaimer than a warning).[7]

Buttressed by its finding that serum sickness was known, foreseeable risk, the district court found that the information sheet provided Petty did not adequately warn him of the risk of serum sickness. We hold that this finding of inadequacy is in accordance with Iowa law and is clearly supported by the evidence. Expert testimony supports Petty's contention that the generality of the warning, especially in the context of the government's unprecedented promotional campaign, was insufficient to have enabled Petty to give an informed consent to receiving the vaccine.[8] Dr. Modell, a

Physician and member of various advisory committees to the Food and Drug Administration, testified that the information form was more an attempt to sell the program than unbiased presentation of the vaccine's risks and benefits. In particular, Dr. Modell testified that "severe or potentially fatal reactions'' says nothing about neurological reaction. Similarly, Dr. Hattwick, Director of the National Influenza Immunization Program Surveillance and Assessment Center, and on the Center for Disease Control Staff of the Bureau of Epidemiology, testified that phraseology decisions were made "to encourage participation." Because those in charge were clearly aware of the specific neurological risks, it was Dr. Hattwick's assessment that they must

have determined that it was more prudent not to mention or stress these risks. He testified that more specificity could have been confusing, by which he meant that participation would have been hampered. Dr. Katz a Professor of Law and Psychiatry at Yale University also testified that the warning was an attempt to induce participation and was inadequate to enable recipients to render an informed consent. On the basis of this testimony, the court could find that under Iowa law, the government's information form inadequately warned the specific known risk of serum sickness.[9]

[6-9] We also reject the government's contention that the reference to death encompasses all risks and their effects on grounds of Iowa law. We

find that in this case Iowa law would mandate that the adequacy of the warning be assessed under the patient rule standard. Compare Cowman v. Hornaday, 329 N.W.2d 422 (Iowa 1983) (patient rule governs physician's duty to disclose the known risk of testicular atrophy to healthy patient seeking a vasectomy purely for socio-economic reasons) with Grosjean v. Spencer, 258 Iowa 685, 140 N.W.2d 139 1966) (professional rule governs physician's duty to disclose risk of peritonitis to severely ill patient). Under the patient rule standard, an individual must be advised of the inherent and potential hazards of the proposed treatment any alternative methods of treatment, the risks attendant to such alternatives, and the likely results of

remaining untreated. See Cowman, 329 N.W.2d at 425; Canterbury v. Spence, 464 F.2d 772 at 787-88; Cobbs v. Grant, Cal.3d 229, 104 Cal.Rptr. 505, 502 P.2d 1, 10 (1972). The duty to disclose is limited not only to reasonably foreseeable risks, but also to material risks. See Cowman, 329 N.W.2d at 425 (quoting Wilkinson v. Vesey, 110 R.I. 606, 627, 295 A.2d 676, 689 1972)). We have found that risk of serum sickness and symptoms was known and that the vaccine subjected healthy recipients to serious debilitating complications. See Petty, 679 F.2d at 723. Moreover, Petty was a healthy person who voluntarily received the vaccine, thus presumably foregoing the vaccination was a viable alternative. Disclosure of the risks would have been "of significance"

to be a vaccinee's decision to be inoculated. Accordingly, we find that the risk of serum sickness and its symptoms was material and, there being no justifiable argument to the contrary, under the patient rule standard, it whould have been dislosed.

[10] We reject the government's contention that a reference to death satisfies its duty to warn for another reason also. Were this undifferentiated warning found to satisfy the duty to warn which under Iowa law requires disclosure of all risks reasonably foreseeable, then the duty to warn would become very hollow indeed. Death can result from virtually any treatment. Moreover, the risk of death may be conceptually remote, whereas a more specific warning detailing the

known risk of serum sickness and its symptoms would alert recipients more concretely to the risks that they actually were assuming. However, the warning given Petty made no attempt to disclose the physiological source of the possible reactions or to advise the recipients of the likely results of foregoing the vaccination, or of any alternative methods of protection and the risks attendant thereto. The patient rule requires the disclosure of these issues in order to obtain an informed consent. The vagueness of the warning, and thus its potential inadequacy, is enhanced by the placement of the warning under ''Special Precautions,'' which implies either that these risks can be guarded against, or that they apply only in special

cases. The disclosure here was merely a broad, generic statement. The alleged warning here did more to dilute the seriousness of the risks at stake than it did to apprise the recipients of the existence of those risks. Indeed, it appears that assuring participation was the motivation behind the phraselogy decisions rather than an effort to inform the recipients of the risks.

[11] Finally, we find that the vagueness of the generic warning is not mitigated by the invitation to ask questions. In some situations and for some individual idiosyncrasies, it may be necessary to rely on recipients' questions to complete the picture of risks and benefits or to clarify issues raised. This was not such a situation. Here the

warning that was given was insufficient to spark the concerns that would have engendered questions. Moreover, it seems unrealistic to believe that the anonymity of a mass immunization context would foster an atmosphere in which questions were likely to be asked or answered thoroughly.

[12] In conclusion, we hold the district court's finding that the warning did not encompass the specific, known, and material risk of serum sickness and its symptoms to be supported by the evidence and is not clearly erroneous. Consequently, under Iowa law it did not provide an adequate basis for Petty to make an intelligent, informed consent.

Causation

[13] To recover Petty also must establish the causal relationship bet-

ween the government's failure to disclose and the injuries he sustained. See Cowman, 379 N.W.2d at 426. The causal relationship exists when it can be shown that had Petty been warned appropriately, he would have foregone the shot. We again look to Iowa substantive law.

It appears that traditionally under Iowa law Petty would have to satisfy a subjective standard of causation to establish liability. Perin v. Hayne, 210 N.W. 2d 609, 618 (Iowa 1973). This would require establishing that he, Robert Petty, would not have been vaccinated had he been adequately warned. The district court, however, applied a rebuttable presumption to the causation issue. The court presumed that, had Petty been adequately warned, he would have acted to

minimize the risk. See Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1281 (5th Cir. 1974). The court relied primarily on the government's "hardsell" approach to the swine flu immunization program to justify the use of a burden-shifting Presumption. Finally, the court relied on Petty's testimony to find that the United States had not rebutted the presumption:

Mr. Petty testified that adequate warnings would have helped him in that they would have enabled him to make a more informed judgment. This testimony provides that the basis for this Court's opinion that Mr. Petty was in fact concerned about making an informed decision. For these reasons, the Court concludes that plaintiff has shown that the failure of the defendant to properly warn was the

proximate cause of plaintiff's injuries. Slip op. at --.

On appeal the Government contends that the district court's prediction that Iowa would not abide by Perin under is undermined by the Iowa Supreme Court's subsequent reaffirmance of the viability of Perin in Cowman. Cowman, 329 N.W.2d at 424. The government contends that Petty has not satisfied the subjective standard of causation as required by Perin. The government relies on Petty's testimony that he did not know what neurological disorders were and his admission that the alleged inadequacies in the informed consent related to matters that would not have enlightened his decision. The government also relies on the opportunity afforded Petty to ask questions. Second,

the government contends that if Reyes is applicable, then the opportunity to ask questions and Petty's testimony which suggests that a warning would not have been enlightening, are sufficient to rebut the causal presumption. In Reyes the Fifth Circuit found that the presumption was not rebutted; however, no warning had been given and no evidence rebutting the presumption had been Presented. The government contends that because a warning, albeit allegedly inadequate, was provided and not needed, any causal connection between the inadequacy of the warning and the plaintiff's injuries is rebutted.

[14] We affirm the district court's application of a rebuttable presumption to the Proximate cause issue. The district

court relied on the factual distinctions between the physician patient situation present in Perin and the mass-immunization context of this case to justify the use of the rebuttable presumption in place of the more traditional subjective standard. Despite the reaffirmance of Perrin in Cowman, the relevant and critical factual distinctions between our case and Perin used to justify the presumption were not Present in Cowman. In contrast to Perin and Cowman, we are presented with a mass immunization case. There were viable alternatives for Petty, yet he received treatment without a warning apprising him of the risks and benefits and without an initial individualized balancing of the risks and benefits by a learned intermediary. Additionally, there is a

public policy consideration favoring allocating the risk of loss among the distributors who can then absorb the cost or distribute it more easily. See Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1294 (5th Cir.), cert. denied, 419 U.S. 1096, 95 S.Ct. 687, 42 L.Ed.2d 688 (1974);10 see also id. at 1294 n. 57 (recognizing view that burden should be born by the government because of the societal benefit bestowed by individuals receiving vaccine). In sustaining the causal presumption, we are also influenced by the "hard-sell" public relations campaign pursued by the government. The campaign not only encouraged participation but also greatly minimized the impact of the warning. See Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977); Reyes v. Wyeth

Laboratories, 498 F.2d 1264 (5th Cir.)., cert. denied, 419 U.S. 1096, 95 S.Ct. 687, 42 L.Ed.2d 688 (1974).

[15] Finally, we affirm the district court's finding that the causal presumption has not been rebutted. The government's distinction between no warning, as in Reyes, and an inadequate warning is unpersuasive. The inadequacies present in the generic warning here do not support the inference that Petty would not have heeded an adequate warning. The warning was inadequate in part because of the calculated ambiguity of its terms and because it was couched in terms that lulled the recipient into a false sense of security. Similarly, the opportunity to ask questions does not in itself rebut the presumption. As addressed earlier, the

anonymity of a mass immunization context does not encourage questions nor was the warning sufficient to spark the concerns necessary to incite meaningful questions. Finally, the district court found, as a finding of fact, that the presumption had not been rebutted. In so finding, the court apparently found Petty's testimony that he would have found more information helpful, more persuasive than the testimony cited by the government. Although different triers of fact may have come to different conclusions, there is substantial evidence in the record to support the court's finding and we cannot say that the court's findng was clearly erroneous. Fed.R.Civ.P. 52(a).

[16] The government also asserts that the district court's attempt to

distinguish Perin in jurisdictional error. The government alleges that its "hardsell" approach was within the discretionary function exemption to the Federal Tort Claims Act, 28 U.S.C. § 2680a) (1970); accordingly, those actions are not a valid jurisdictional basis for the imposition of liability. The actions of the President of the United States in his attempts to sell the program, however, were not used as a basis of imposing liability. The evidence was used to support the application of a burden-shifting presumption. Thus, reliance on these actions is not jurisdictional error. Accordingly, we find that the government is liable under a negligence theory to Petty for the injuries he sustained as a result of his swine flu inoculation.

Strict Liability

Alternatively, the district court found that the drug manufacturer, Merrill-National, had a duty to warn the ultimate recipient of the vaccine. Furthermore, the district court found that Iowa, if presented with the facts of the instant case, would hold the drug manufacturer strictly liable for a breach of its duty to warn. The district court relied on Iowa's adoption of Section 402A of the Restatement (second) of Torts, see Hawkeye Security Ins. Co. v. Ford Motor Co., 174 N.W.2d 672, 684 (Iowa 1970), and of comment j thereto, see Cooley v. Quick Supply Co., 221 N.W.2d 763 (Iowa 1974), to reason that Iowa also would adopt comment k to Section 402A. Comment k recognizes that some products,

such as drugs, are unavoidably unsafe; however, because their benefits outweigh the risks, if properly prepared and accompanied by proper warnings, the product is, by definition, neither defective nor unreasonably dangerous. The swine flu vaccine would thus be classified as a justified, but unavoidably unsafe product however, because the warning was inadequate, the vaccine was unreasonably dangerous, rendering the drug manufacturer strictly liable. Because Merrill-National was a "program participant," 42 U.S.C. § 247b(k)(2)(B) "program participant" includes, inter alia, the manufacturer of the swine flu vaccine), the liability scheme of the Swine Flu Act imposes this liability on the United States. See id, at §

247b(k)(7). On appeal, the government contends that the drug manufacturer did not have a duty to warn. It argues that section 247b(j)(1)(F), which authorizes the Secretary to develop and implement a written informed consent, statutorily places the sole duty to warn on the government.[11] Thus, any defect or inadequacy of the warning should be attributed solely to the government. Because the government's liability for its own acts or omissions is assessed under the Federal Tort Claim Act, see 42 U.S.C. § 247b(k)(2)(A), Petty is limited to a negligence claim. See Dalehite v. United States, 346 U.S. 15, 73 S.Ct. 956, 97 L.Ed. 1427 (1953).

[17, 18] We affirm the district court's holding that Iowa law would impose

a duty to warn on the drug manufacturer, and that duty to warn would extend to the ultimate consumer in a mass immunization case. See, e.g., Stanback v. Parke, Davis & Co., 657 F.2d 642, 646-47 (4th Cir. 1981); Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977); Reyes v. Wyeth Laboratories, Inc., 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096, 95 S.Ct. 687, 42 L.Ed.2d 688 (1974); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968). Moreover, we affirm the finding that Iowa would hold the drug manufacturer strictly liable for the breach of this duty if presented with such a case. See Hawkeye Security Ins. Co., 174 N.W.2d 672 (Iowa 1970); Kehm v. Procter & Gamble, 724 F.2d 613 (8th Cir.

1983; see also Aller v. Rodgers Machinery Mfg. Co., 268 N.W.2d 830 (Iowa 1978).

[19] We recognize that the government has attempted to statutorily assume the duty to warn the vaccinees, however, we do not find that this delegation thereby relieves the manufacturer from liability for any resulting inadequacy of the warning. The duty to warn is imposed on the manufacturer and in a mass immunization context, where there is no learned intermediary, the duty extends to the ultimate recipient of the vaccine. Delegation of the duty does not, in itself, relieve the manufacturer of its obligation, nor should it insulate the manufacturer from the liability for deficiencies in the manner in which the chosen

intermediary effectuates the manufacturer's duty. Although on the side lines, Merrill-National is assumed to have had knowledge of the warning issued and to have had the ability to affect the warning.

In defending against liability for its own acts or omissions in the warning, the government argued that it had no duty to warn of the risk of serum sickness and its symptoms because they were not foreseeable. The government urges that for duty to warn cases involving drugs, negligence and strict liability are functionally and analytically similar causes of action; therefore, the same lack of foreseeability of the risk should relieve the drug manufacturer for any liability for the lack of a warning of the risk.

See Deluryea v. Winthrop Laboratories, 697 F.2d 222 (8th Cir. 1983). As a factual matter, we have found that the evidence supports the district court's finding that serum sickness was a foreseeable risk. Whether this finding is supported by the evidence, however, is irrelevant to the program participant's liability for failure to warn under a strict liability theory under Iowa law.

[20] As the government contends, the Deluryea panel did find that a strict liability action for failure to warn was similar to one based on negligence where drugs are involved. This finding was based on Arkansas law, as reflected in the district court's jury instruction, which had injected notions of foreseeability into the determination of strict liabi-

lity. Here we apply Iowa law. While recognizing that the terminology in negligence and strict liability actions may be similar and that the terminology "rings in negligence," Iowa clearly recognizes the analytical distinction between the two causes of action in duty to warn cases. Aller v. Rodgers Machinery Mfg. Co., 268 N.W.2d 830, 834-36 (Iowa 1978); see also Sterner v. U. S. Plywood Champion Paper, Inc., 519 F.2d 1352, 1354 (8th Cir. 1975); of Kehm v. Proctor & Gamble, 724 F.2d 613 (8th Cir. 1983) (Lay, C.J., concuring). In Aller, the Iowa court explicitly recognized the difference between the two theories of liability, stating:

> In strict liability the plaintiff's proof concerns the condition

(dangerous) of a product which is designed or manufactured in a particular way. In negligence of the proof concerns the reasonableness of the manufacturer's conduct in designing and selling the product as he did. Phillips v. Kimwood Machine Co., 269 Or. 485, 493-95, 525 P.2d 1033, 1037 (1974).

Id. at 835 (emphasis added). Accordingly, negligence liability focuses on whether the defendant-manufacturer knew or should have known of some foreseeable harm arising from the use of the product. In contrast, a strict liability action focuses not on the manufacturer's conduct or knowledge, but on whether the product, as marketed, is defective. In order to focus on the product in strict

liability actions, courts have imputed knowlege of risk to the manufacturer. See, e.g., Phillips v. Kimwood Machine Co., 269 Or. at 492, 525 P.2d at 1036. The relevant question is then whether the product "is so harmful to persons [or property] that a reasonable prudent manufacturer [supplier] with this knowledge would have not placed it on the market." Robbins v. Farmers Union Grain Terminal Ass'n., 552, F.2d 788, 795 n. 15 (8th Cir. 1977) (quoting Phillips v. Kimwood Machine Co., 525 P.2d at 1040-41 n. 16), see also Aller, 268 N.W.2d at 836 (equating Phillips' test, with its emphasis on the seller, with the consumer-exceptions test applied in Iowa). Applied to our case, we determine the drug manufacturer's liability under strict liabi-

lity, by assuming knowledge of the risk of serum sickness. Then the issue is whether the manufacturer, with such knowledge, has distributed an unreasonably dangerous product. In light of comment k of section 402A, the unreasonable dangerousness of this unavoidably unsafe product turns on whether the warning given with the product adequately apprises the recipient of those dangers. This issue has already been resolved: the warning is inadequate to apprise Petty of the known risk of serum sickness and its symptoms.

We have found that Merrill-National had a duty to warn Petty and that the warning was inadequate to discharge its duty. Administered without an adequate warning, the swine flu vaccine was defective, hence unreasonably dangerous. Had

the manufacturer warned of serum sickness, the warning would presumably have had the same effect as one issued by the government Accordingly, we simply adopt our earlier finding that the lack of an adequate warning was the proximate cause of Petty's injuries. See supra 1437-39.

[21, 22] Under Iowa law, Merrill-National would have been held strictly liable for its distribution of a defective product which proximately caused Petty's injuries. Accordingly, in addition to holding the government liable for, its own negligence, we alternatively hold the United States derivatively liable for at 1040-41 n. 16), see also Aller, 268 N.W.2d at 836 (equating Phillips' test, with its emphasis on the seller, with the consumer-exceptions test applied in Iowa).

Applied to our case, we determine the drug manufacturer's liability under strict liability, by assuming knowledge of the risk of serum sickness. Then the issue is whether the manufacturer, with such knowledge, has distributed an unreasonably dangerous product. In light of comment k of section 402A, the unreasonable dangerousness of this unavoidably unsafe product turns on whether the warning given with the product adequately apprises the recipient of those dangers. This issue has already been resolved: the warning is inadequate to apprise Petty of the known risk of serum sickness and its symptoms.

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[21, 22] Under Iowa law, Merrill-National would have been held strictly liable for its distribution of a defective product which Proximately caused Petty's injuries. Accordingly, in addition to holding the government liable for its own negligence, we alternatively hold the United States derivatively liable for Merrill-National's liability under strict liability[12]. 42 U.S.C. §247(b)(2)(A)(i).

BRIGHT, Circuit Judge, dissenting.

I dissent. I believe that the warning Petty received before being vaccinated was adequate. Therefore the United States is not liable under either the negligence theory or the strict liabilty theory propounded by the majority.

Even assuming that serum sickness was a foreseeable risk attending swine flu vaccination, I think vaccines received adequate warning. The information form Petty read stated that, ''[as with any vaccine or drug, the possibility of severe or potentially fatal reactions exists.'' I do not think that a more specific warning, either describing the symptoms of serum sickness or mentioning that condition by

name, would have served any useful purpose in the context of this mass inoculation program. Vaccinees were warned that a small risk of severe or fatal reaction accompanied receiving the vaccine. The majority does not dispute the minimal nature of that risk, but maintains that the warning should have itemized the potential adverse reactions from the vaccine. Yet the warning of the "possibility of severe or potentially fatal reactions" more directly, completely and graphically describes for the lay person the hazards of receiving the vaccine than a specific itemization of adverse effects. I agree with the government and with most courts that have considered the issue, see supra n. 6, that a detailed catalogue of every serious complication that befall a vac-

cinee would have been counterproductive, serving to confuse or needlessly alarm potential vaccinees without giving them any more information necessary to the making of an informed decision. I therefore reject the majority's conclusion that the failure to specify the potential adverse effects of the vaccine makes warning inadequate when, as here, the warning aptly apprised vaccinees of the overall possibility of harm.

Because the warning was adequate, the government was not negligent. Nor is the government strictly liable under the theory that the unavoidably unsafe vaccine was rendered defective or unreasonably dangerous by the failure to give a more detailed warning.

I think the practical consequence of the court's decision is to impose so stringent a warning requirement as likely to render any future mass inoculation program infeasible, no matter how desirable.

Accordingly, I dissent.

FOOTNOTES

1. A more thorough discussion of the facts can be found in Judge Bright's earlier opinion. 679 F.2d at 722-24. For a more extensive discussion of the history and purpose of the swine flu program, see Sparks v. Wyeth Laboratories, Inc., 431 F.Supp. 411 (W.D. Okla. 1977), and Unthank v. United States, 732 F.2d 1517 (10th Cir. 1984). Under the liability Provisions of the Act, the United States is substituted as the defendant in the place of any "program participant," i.e. a vaccine manufacturer, in any action for injuries or death resulting from the Swine Flu Program. 42 U.S.C. § 247b(k)(1)(B), (k)(3). For actions based on the act or omission of a program participant, the United States is subject to liability on any ground or theory that the program participant, the United States is subject to liability on any ground or theory that the program participant would be held liable under the law of tHe state where the act or omission occurred. Id. at § 247b(k)(2)(A)-(k)(3). Where tHe government is held liable for negligent actions of a program participant, the government has a right of action over that program participant; however, for any liability sustained against a program participant on strict liability theory, the govern-

ment sits ''in the shoes" of the program Participant and bears any costs. See id. at § 247b(k)(7). Concurrently, the Act subjects the United States to liability for its own acts or omissions under the strictures of the Federal Tort Claims Act accordingly, the government's liability is limited to negligent actions. Id. at § 247b(k)(2)(A)

2. On appeal, the government contests the district court's apparent linking of serum sickness and neurological reactions. The government's Primary thrust appears to be that there exists no evidence that abortive neuropathy is a known disease or that Petty in fact suffered from it or a neurological disease; therefore, evidence bearing on the government's awareness of neurological reactions is not relevant to the reeasonable foreseeability of serum sickness. The plaintiff characterizes abortive neuropathy as a nervous disorder that accompanies serum sickness. Explaining his diagnostic characterization of Petty's illness as an ''abortive neuropathy''. Dr. Hyden, Petty's treating physican, stated that Petty's initial symptoms "were those of ascending neuropahty, but this did not progress. It did not continue and become worse. Instead, it went away or became submerged in his symptoms of myalgia and

arthralgia, and so it started out but it did not continue." Tr. at 119-20. We are satisfied that Dr. Hyden was not using "abortive neuropathy" to depict a specific disease, but rather was using it as a descriptive phrase in his diagnosis in the sense that the disease began as a neurological condition but did not progress as such.

At the trial level the government asserted that the specific ailment that Petty sustained was not critical because, regardless of whether it was described as a neurological complication or a serum sickness, it was a "severe reaction", of which he was adequately warned. In his opening statement at trial, counsel for the government stated to the court:

> Now, whether we said "neurological complications" or that he might get serum sickness reaction or autoimmune reprercussions, the diagnoses that might be Possible that he's complained of following the administration of the drug is immaterial, as long as we said it was a severe reaction. And I think that in terms of--without going to the question of causation of the symptoms, that the symptoms were in fact a severe reaction; and the government would admit that they symptoms he complained of were a severe reactions.

Thus, at trial no serious contention was made by the government or its witnesses, that serum sickness did not involve neurological symptoms or effects.

3. The warning provided to Petty reads as follows:

> IMPORTANT INFORMATION
> ABOUT SWINE INFLUENZA
> (FLU) VACCINE
> (MONOVALENT)
> July 15, 1976
> The Disease
> Influenza (flu) is caused by viruses. When People get flu they may have fever, chills, headache, dry cough or muscle aches. Illness may last several days or a week or more, and complete recovery is usual. However, complications may led to pneumonia or death in some people. For the elderly and people with diabetes or heart, lung, or kidney diseases, flu may be especially serious. It is unlikely that you have adequate natural Protection against swine flu, since it has not caused widespread human outbreaks in 45 years. The Vaccine will not give you flu because it is made from killed viruses. Today's flu vaccines cause fewer side effects than those used in the past. In contrast with some other vaccines, flu vaccine can be taken safely during pregnancy.

One shot will protect most people from swine flu during the next flu season; however, either a second shot or a different dossage may be required for persons under age 25. If you are under 25 and a notice regarding such information is not attached, this information will be provided to you wherever you receive the vaccine.

Possible Vaccine Side Effects

Most people will have no side effects from the vaccine. However, tenderess at the site of the shot may occur and last for several days. Some People will also have fever, chills, headache, or muscle aches within the first 48 hours.

Special precautions

As with any vaccine or drug, the possibility of severe or potentially fatal reactions exists. However, flu vaccine has rarely been associated with severe or fatal reactions. In some instances people receiving vaccine have had allergic reactions. You should note very carefully the following precautions:

Children under a certain age should not routinely receive flu vaccine. Please ask about age limitations if this information is not attached.

People with known allergy to eggs should receive the vaccine only under special medical supervision.

People with fever should delay getting vaccinated until the fever is gone.

People who have received another type of vaccine in the past 14 days should consult a Physician before taking the flu vaccine.

If you have any questions about flu or flu vaccine please ask.

Petty also signed the following registration form, which was attached to the information sheet:

REGISTRATION FORM

I have read the above statement about swine flu, the vaccine, and the special precautions. I have had an opportunity to ask questions, ... and understand the benefits and risks of flu vaccination. I request that it be given to me or to the Person named below of whom I am the the parent or guardian.

4. The Iowa Informed Consent law creates a Presumption of informed consent when the statutory prerequisites are satisfied. The statute provides:

> A consent in writing to any medical or surgicial procedure or course of procedures in patient care which meets the requirements of this section shall create a presumption that informed consent was given. A consent in writing

meets the requirements of this section if it:

1. Set forth in general terms the nature and purpose of the procedure or procdures, together with the known risks, if any, of death, brain damage, quadriplegia, Paraplegia, the loss or loss of function of any organ or limb, or disfiguring scars associated with such procedure or procedures, with the probability of each such risk if reasoanbly determinable.
2. Acknowledges that the disclosure of that information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner.
3. Is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent, is signed by a person who has legal authority to consent on behalf of that patient in those circumstances.

5. Serious questions are raised about the applicability of the statute. For example, it is not clear whether a vaccine recipient in a mass immunization context is a

"patient'' undergoing "patient care''.

6. See Daniels v. United States, 704 F2d 587 (11th Cir. 1983) (Alabama law) (warning was "reasonable"). The following district courts also found that a warning of potentially severe or fatal reactions encompasses more specific reactions, such that the inclusion of the words neurological disorders would have been superfluous. See, e.g., Butler v. United States, 80-3110 (S.D.W.Va. May 18, 1983); Gilroy v. United States, No. 79-597 (M.D.Pa. June 16, 1983) (Pennsylvania law); Bean v. United States, 533 F.Supp. 567 (D. Colo. 1980) (Colorado law).

7. The government contends that Claxton does not support Petty's case. First, the plaintiff in Claxton sustained Guillain-Barre Syndrome (GBS). Because the government has conceded liability in GBS cases, see, e.g., Overton v. United States, 619 F.2d 1299 (8th Cir. 1980), the court's discussion of the adequacy of the warning was dictum. Second, the government contends that Claxton is undermined by subsequent Fifth Circuit rulings to the contrary in Daniels v. United States, 704 587 (11th Cir. 1983) (warning was

reasonable under Alabama law) and in Freeman v. United States, 704 F.2d 154 (5th Cir. 1983) (risk of adhesive capsilitus not foreseeable enough to require a warning). Both of these cases are distinguishable and not persuasive. In Daniels the, court applied Alabama law, which imposes a reasonableness" standard. Iowa law, however, applies a more stringent disclosure standard under the patient rule. Freeman applied Texas law, as did Claxton; however, the Fifth Circuit found that no warning of the Possibility of plaintiff's malady was required, therefore, the Fifth Circuit's discussion of the adequacy of the warning is also dictum, and we find that it less relevant or persuasive dictum than in Claxton.

8. Although we recognize the hardshell campaign as it bears on the context, and therefore, the adequacy of the warning, we emphasize that we are not passing on the government's good faith in its promotional efforts or on the ultimate necessity of the program.

9. We also note that the government has conceded that the swine flu vaccine can cause GBS. Stipulation and Final Pretrial

Order, Paragraph IX In Re Swine Flu Immunization and Products Liability Litigation M.D.L. No. 330, Mis. No. 78-0040 (D.D.C. 1979). Explaining why the government decided to provide compensation to GBS sufferes merely upon an adequate causation presentation, Secretary Califano stated:

> First, the informed consent form ... did not warn individuals that there was a one in one hundred thousand risk that a person receiving a flu shot would contract Guillain-Barre and that one in every two million would die from the condition ... Second, in the Swine Flu program, the Federal Government, in an unprecedented effort actively urged millions of Americans to get flu vaccination shots and funded the nationwide campaign.

Statement of Secretary Califano (June 20, 1978). If the dissent is correct that the warning provided Petty was adequate to apprise him of the risk of serum sickness, we fail to see way it is inadequate to apprise of the risk of GBS.

10. Reyes, the Fifth Circuit also justified the causal presumption by recognizing that testimony as

to what have been done had there been an adequate warning would have been self-serving and speculative. Reyes, 498 F.2d at 1281-82.

11. We recognize that both the government and the drug manufacturers intended thegovernment to assume the duty to warn. See 42 U.S.C. § 247b(j)(1)(F); cf. Cong.Rec., August 10, 1976 at 26799 (Rep. Rogers relating that the manufacturers wanted to clarify that the duty to warn vaccinees, which had been put on the manufacturer in the Davis and Reyes polio cases, would lie with the government); see also Cong.Rec. August 10, 1976 at 26802, 26815.

12. We note that this holding does not defeat the Congressional intent to immunize drug manufacturers from unlimited liability exposure. By virtue of the liability scheme presented in the Swine Flu Act the burden of both defending this action and the resulting damages is born by the United States. See 42 U.S.C § 247b(2)(A)(i); see also Unthank v.United States, 732 F.2d 1517 (10th Cir. 1984) (alternatively holding government derivately liable for manufacturer's strict liability based on Congressional intent to assure

compensation for all persons injured by the swine flu vaccination).

Iowa Informed Consent Statute

Iowa Cose § 147.137 (1975)

IOWA CODE § 147.137(1975).

"A consent in writing to any medical or surgical procedure or course of procedures in patient care which meets the requirements of this section shall create a presumption that informed consent was given. A consent in writing meets the requirements of this section if it:

"1. Sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, or disfiguring scars associated with such procedure or procedures, with the probability of each such risk if reasonably determinable.

"2. Acknowledges that the disclosure of that information has been

made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner.

"3. Is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent, is signed by a person who has legal authority to consent on behalf of that patient in those circumstances."

Louisiana Informed Consent Law

LSA R.S. 40:1299.40

LA R.S. § 1299.40. CONSENT TO MEDICAL TREATMENT

A. Notwithstanding any other law to the contrary, written consent to medical treatment means a consent in writing to any medical or surgical procedure or course of procedures which (a) sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, of disfiguring scars associated with such procedure or procedures, (b) acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner, and (c) is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent by

a person who has legal authority to consent on behalf of such patient in such circumstances. Such consent shall be presumed to be valid and effective, in the absence of proof that execution of the consent was induced by misrepresentation of material facts.

B. Except as provided in Subsection A of this Section, no evidence shall be admissible to modify or limit the authorization for performance of the procedure or procedures set forth in such written consent.

C. Where consent to medical treatment from a patient, or from a person authorized by law to consent to medical treatment for such patient, is secured other than in accordance with Subsection A above, the explanation to the patient or to the person consenting for such patient shall include the matters set forth in Paragraph (a) of

Subsection A2 above, and an opportunity shall be afforded for asking questions concerning the procedures to be performed which shall be answered in a satisfactory manner. Such consent shall be valid and effective and is subject to proof according to the rules of evidence in ordinary cases.